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SENATE

REPORT
104–364

NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1996

SEPTEMBER 9, 1996.—Ordered to be printed

Mrs. KASSEBAUM, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 1897]

The Committee on Labor and Human Resources, to which was referred the bill (S. 1897) to amend the Public Health Service Act to revise and extend certain programs relating to the National Institutes of Health, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill (as amended) do pass.

CONTENTS

I. SUMMARY OF THE BILL

TITLE I—PROVISIONS RELATING TO THE NATIONAL INSTITUTES OF HEALTH

Director's discretionary fund (sec. 101)

This provision reauthorizes the discretionary fund for the Director of the National Institutes of Health (NIH).

Children's vaccine initiative (sec. 102)

This provision reauthorizes the children's vaccine initiative.

TITLE II—PROVISIONS RELATING TO THE NATIONAL RESEARCH INSTITUTES

Research on osteoporosis, Paget's disease, and related bone disorders (sec. 201)

This provision reauthorizes research initiatives in osteoporosis, Paget's disease, and related bone diseases.

Establishment of National Human Genome Research Institute (sec. 202)

This provision elevates the National Center for Human Genome Research to institute status by the establishment of the National Human Genome Research Institute (NHGRI). This will ensure a continued focus of NIH resources on important genetic research. It continues the commitment of the NIH to ethical, legal, and social issues relative to genome research by maintaining a set-aside of at least 5 percent of NHGRI extramural research funds for research in these areas.

Increased amount of grants and other awards (sec. 203)

This provision increases from $50,000 to $100,000 the amount that an institute can grant on the basis of technical and peer review alone. Grants greater than $100,000 will continue to require advisory council approval. This proposal would eliminate duplication of the approval process beyond that of peer review for small grants and would accelerate funding of new, cutting-edge proposals. Meetings of advisory committees and councils and application of Federal Advisory Committee Act (sec. 204)

This provision allows the convening of advisory councils and committees on an as-needed basis, instead of three to four times a year as currently required by law. This change would permit the NIH to reduce the expense associated with bringing advisers and committee members to Bethesda, MD, several times a year. These groups already take advantage of telecommunications technology for timely discussion and decision making.

The application of the provisions of the Federal Advisory Committee Act to peer review committees is eliminated, thus reducing this administrative burden. The provisions of this act continue to apply to all other advisory committees and councils of the NIH.

Elimination or modification of reports (sec. 205)

The bill increases administrative efficiency by eliminating the requirement for reports that are duplicative or unduly burdensome.

The reports that are eliminate or modified include: the biennial report of the Director, NIH, to Congress and the President; the annual report of the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee; the annual report of the Skin Diseases Interagency Coordinating Committee; the annual report of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board; the Secretary's annual report to Congress on Health Services Research relating to alcohol abuse and alcoholism, drug abuse, and mental health; the Secretary's triennial report to Congress on drug abuse; two annual reports to Congress on Sudden Infant Death Syndrome Research; the reports of the Coordinating Committees of Digestive Diseases, Diabetes Mellitus, and Kidney, Urologic and Hematological Diseases; the report of the U.S.-Japan Cooperative Medical Science Program; and the report of the Task Force on Aging Research. It also converts the schedule for the report on disease prevention from annual to biennial.

TITLE III—SPECIFIC INSTITUTES AND CENTERS

National Cancer Institute (secs. 301–302)

The bill authorizes $3 billion for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999 for general funding for the National Cancer Institute.

In addition, it specifically reauthorizes programs in breast cancer, other gynecologic cancers, prostate cancer, and the conditions associated with exposure to the drug diethylstilbestrol.

National Heart, Lung, and Blood Institute (sec. 311)

The bill authorizes $1.6 billion for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999.

National Institute of Allergy and Infectious Diseases (secs. 321–322)

The bill reauthorizes the research initiative in tuberculosis and the Terry Beirn Community-Based AIDS Research Initiative.

National Institute of Child Health and Human Development (sec. 331)

This provisions reauthorizes the Centers for Contraception and Infertility.

National Institute on Aging (sec. 341)

The bill authorizes $550 million for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999.

National Institute of Alcohol Abuse and Alcoholism (secs. 351–352)

The bill authorizes $330 million for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999.

Section 352 corrects an omission from earlier authorization language regarding the definition of "construction" for use with reference to the National Institute of Alcohol Abuse and Alcoholism.

National Institute on Drug Abuse (secs. 361–363)

The bill authorizes $480 million for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999.

In addition, the medication development program is authorized. Section 363 corrects an omission from earlier authorization language regarding the definition of "construction" for use with reference to the National Institute on Drug Abuse.

National Institute of Mental Health (sec. 371)

The bill authorizes $750 million for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999.

National Center for Research Resources (secs. 381–384)

The bill reauthorizes support for construction and modernization of biomedical and behavior research facilities from approved grants. It requires a larger matching component from grantee institutions in that the amount provided by Federal funds is reduced from 50 percent to 40 percent for research facilities and from 40 percent to 30 percent for multipurpose facilities.

To provide the infrastructure for clinical research and clinical research training, the bill authorizes support for the general clinical research centers located throughout the country.

To address the need for expanded involvement in clinical research, the bill establishes clinical research career enhancement awards to support individual careers in clinical research. In addition, it establishes innovative medical science awards to support individual clinical research projects.

National Library of Medicine (secs. 391–392)

The bill authorizes $160 million for fiscal year 1997 and such sums as necessary for fiscal years 1998 and 1999. It also increases the cap on individual extramural grants from the National Library of Medicine to $1.25 million.

TITLE IV—AWARDS AND TRAINING

Medical Scientist Training Program (sec. 401)

The Medical Scientist Training Program supports professional education for students who intend to pursue careers in academic medicine. This provision expands the fields in which students may study in this program. It does so by broadening the program to include the option of a doctoral degree in certain nonbiologic science disciplines, for example, biostatistics, epidemiology, economics, or bioethics.

General loan repayment (secs. 402–404)

The bill raises the maximum level of qualified loan repayments from $20,000 to $35,000 for each year of service for appropriately qualified health professionals conducting research training as employees of the NIH. These changes relate to established programs with respect to AIDS, contraception and infertility, programs for research generally, and clinical research programs for individuals for disadvantage backgrounds. In addition, it establishes a general loan repayment program to be under the direction of the Director of NIH. The Director will annually designate the fields of research that will be included in this program.

Section 404 would increase from 50 to 100 the total number of contracts for scholarships and loan repayments that the Secretary may provide through the Undergraduate Scholarship Program Regarding Professions Needed By National Research Institutes, and the Loan Repayment Program Regarding Clinical Researchers From Disadvantaged Backgrounds. Moreover, the sites where such training may take place are expanded beyond the NIH campus to include clinical research training positions at General Clinical Research Centers and other extramural sites. At least 50 percent of these awards will go to health professionals from disadvantaged backgrounds.

TITLE V—RESEARCH WITH RESPECT TO AIDS

Comprehensive plan for expenditure of AIDS appropriations (sec. 501)

This provision reauthorizes the research program regarding AIDS and continues its administration through the Office of AIDS Research.

Emergency AIDS discretionary fund (sec. 502)

The bill reauthorizes an emergency AIDS discretionary fund that is available to the Director of the Office of AIDS Research for projects of significant need.

TITLE VI—GENERAL PROVISIONS

Authority of the Director of the NIH (sec. 601)

The bill gives the Director of the NIH the authority to establish intramural training programs and gives the Director the authority to hire and compensate health care professionals at a level similar to the Department of Veteran Affairs.

Office of Rare Disease Research (sec. 611)

The bill codifies the Office of Rare Diseases, which currently exists in the Office of the Director of the NIH. The purpose of this office is to promote and coordinate the conduct of research on rare diseases through a strategic plan and to establish and manage a rare disease research clinical database.

Certain reauthorizations (secs. 621–622)

The bill reauthorizes the research training programs funded as the National Research Service Awards and the nonprofit corporation known as the National Foundation for Biomedical Research.

Miscellaneous provisions (secs. 631–636)

Section 631 takes a first step toward establishing additional sources of funding for biomedical research at the NIH by creating a National Fund for Health Research in the U.S. Department of the Treasury. This trust fund would be on budget. A source of revenue for the fund is not provided.

A definition of clinical research is provided for reference throughout the bill.

The bill amends the Senior Biomedical Research Service retirement provisions to enable the Secretary of Health and Human

Services to make contributions as a nonprofit entity to the academic retirement systems in which members participated immediately prior to their appointment in the Service.

Section 634 authorizes a pediatric research initiative. It authorizes $50 million over fiscal years 1997 through 1999, to be available to the Director of the NIH to encourage increased support across a broad spectrum of pediatric research areas.

Section 635 authorizes increased funding specifically for research focused on diabetes.

The bill provides for an initiative for research in Parkinson's disease. It would establish up to 10 Morris K. Udall Research Centers for interdisciplinary study of the cause and treatment of Parkinson's disease. In addition, it would establish Morris K. Udall Awards for Innovation in Parkinson's Disease Research to support innovative proposals for research in this field.

Repeals and conforming amendments (sec. 641)

This provision makes corrections in current law regarding references to the National Institute for Nursing Research and the Under Secretary for Health of the Department of Veterans Affairs.

In addition, it repeals a number of duplicative advisory boards and committees, including the National Diabetes Advisory Board, National Digestive Diseases Board, National Kidney and Urologic Diseases Advisory Board, National Arthritis and Musculoskeletal and Skin Diseases Advisory Board, National Deafness and Other Communications Disorders Advisory Board, National Commission on Alcoholism and Other Alcohol Related Problems, and Advisory Council on Hazardous Substances Research and Training.

II. Background and Need for Legislation

GENERAL

Funding for the National Institutes of Health (NIH) in the waning 20th century cannot be considered separate from the broader issues of health care delivery in the United states. A recent report from the Institute of Medicine of the National Academy of Sciences noted, "the escalating costs of health care and the large number of uninsured and underinsured people in the United States have thrown health care issues into the policy arena at all levels of government."

Policies that shape authorizing legislation for the NIH are influenced by two overarching issues. First is the ever-expanding base of biomedical knowledge which creates new promises and countless creative research opportunities. Researchers in academic health centers (AHC's) around the country—researchers who depend on grants from the NIH for sustenance—generate four times as many approved proposals for support by the NIH than can be funded by the available budgeted dollars.

Second, the academic medical community—where the bulk of basic biomedical research takes place—is posed with an unprecedented challenge: how will AHC's maintain their research mission in the context of the competitive health care marketplace in which they now exist. The clinical practice environment has traditionally provided an important arena for the research and education roles

of AHC's. In addition, fees from faculty practice plans have provided cross-subsidies for the academic mission of many AHC's. The cost of research and education places AHC's at a disadvantage in the competition for managed care contracts. Consequently, the very task that distinguishes these academic health institutions places them at a market disadvantage among their nonacademic competitors and threatens their ability to continue their mission.

HISTORY OF THE NIH AND ITS FUNDING

After a half century of research in Public Health Service laboratories, the NIH, as we know it today, had its birth in 1930. It moved to its present site in Bethesda, MD in 1938. World War II gave biomedical research a substantial boost that led to extramural funding—funding that is in the form of grants to universities, hospitals, and other research institutions.

Extramural research grants are funded based on a systematic process that requires approval by expert colleagues of the proposed research concept and plans before consideration for funding. This peer-review process is at the heart of the NIH research funding process. This has been enormously successful in evaluating the scientific and technical merit of proposals, which supports the awarding of the most meritorious projects. This process brings together acknowledged experts who review proposals for research funding in their respective scientific fields. Based on their own expertise, they make decisions on the abilities of investigators to be successful in their proposals, as well as on the creativity of their proposals. Subsequently, the advisory councils of the NIH Institutes and Centers review the approved proposals for program relevance and appropriateness of the scientific and technical review.

After World War II, debates began in Congress underscoring the tension between research autonomy, on the one hand, and greater public control of research spending, on the other. This discussion continues to this day.

The NIH moved forward from the post-war era with a growth rate that doubled research support every 5 years until 1990. However, inflation and the effort to balance the Federal budget have curbed this growth rate.

Regarding inflation, Dr. Harold Varmus, the Director of the NIH, has acknowledged that Federal funding for biomedical research has entered an era of steady-state funding. The Bureau of Economic analysis in the U.S. Department of Commerce defines the price index for biomedical research as the Biomedical Research and Development Price Index (BRDPI). This index represents the expenditure weights that are constituted by unique costs of biomedical research—variables such as indirect costs of administration for research and other costs of high technology. Consistently, BRDPI has always been higher than general inflation. Therefore, to maintain steady-state funding, Federal funding for the NIH will have to be greater than general inflation.

During the first session of the 104th congress, the NIH fared well. The continuing resolution that funded the NIH for fiscal year 1996 provided a 5.7 percent increase. It is unlikely that such a rate of growth can be sustained in the future given the budget pres-

sures of other discretionary domestic spending, as well as the pressure created by ever-increasing entitlement spending.

POLICY ISSUES AND REAUTHORIZATION OF THE NIH

Four broad issues have been central to the discussions leading up to reauthoriztion legislation for the NIH in the 104th Congress: first, the conflict between earmarked research and investigator-initiated research funding; second, the perceived diminished role for clinical research compared to basic research funding; third, a need for administrative simplification and efficiency to free up scarce dollars for grant-making; and finally, concern about the educational preparation of future biomedical researchers.

1. Earmarks versus investigator-initiated research

Earmarks for specific research programs have traditionally driven funding for new initiatives. A recent trend in research funding has been for preferential support for promising efforts arising from investigator-initiated research. This was the implication of testimony from several witnesses at hearings conducted by the Senate Committee on Labor and Human Resources in March 1996. This argument found its voice in the markup of S. 1897, where members of the committee acknowledged the difficulty inherent in a process where Congress calls for more programs while the overall budget for the NIH has little growth. Such a predicament creates the tension of a request for new areas of investment by the authorizing committee but an inability to provide resources by the appropriators.

2. Basic versus clinical research

Basic research is the pursuit of fundamental biomedical mechanisms, proceeding from one discovery to the next, driven by the pursuit of knowledge for its own sake. Clinical research describes the fields of research that are patient-focused. Clinical research applies basic research to patient care. Over time, the line between basic research and clinical research migrates toward basic research. As the molecular understanding of biomedical processes expands, the research opportunities in basic research tend to crowd out ideas for clinical research that compete for limited research dollars.

The Director of the NIH has acknowledged a need for attention to the issues related to clinical research by appointing a panel on clinical research. This panel has begun its deliberations and will provide a series of recommendations that are based on the evolving contest in which biomedical research is funded.

In practical terms, some feel the success of the discoveries into the understanding of basic mechanisms of biology and the molecular explanation of disease has fueled a commitment by study sections—those committees made up of peers who determine the merit ranking of submitted grants—to basic research. Clinical investigators have been less successful in competition with basic scientists for grant dollars. NIH is examining the issue of whether the composition of study sections has an influence on the success of these applications and what actions may need to be taken in this area.

3. Administrative simplification and efficiency

Over the years, there has been a sense that increasing administrative burdens, many created by Congress, expend resources that could be better spent on research grants. The requirements for formal reports to Congress, while well-intentioned with regard to protecting the taxpayers' investment, may have lost their value compared to newer and faster methods of keeping Congress informed. Reports that take months or years to produce, in traditional preparation and publication cycles, may be less useful than more specific response to timely questions from members of Congress. The annual appropriations process and the triennial authorization process provide just-in-time responses for those committees of jurisdiction on whom the responsibility for funding falls.

In another context, reports from committees and councils of the NIH might be replaced in some instances by the publication of meeting minutes, or the electronic transmission of conclusions.

Mandated meeting frequencies of advisory councils and committees could be replaced by as-needed meetings and the use of telecommunications technology and electronic communication for decision making.

4. Education and training of future biomedical scientist

A growing concern is that medical graduates are shying away from the pursuit of careers in clinical research. The increasing cost of a medical education is said to discourage medical graduates from the prolonged training required for such careers. The average education loan for graduating physicians in 1996 is over $60,000. The insecurity of funding for clinical research and the reduced compensation associated with careers in research, compared to careers in clinical practice, often discourage young medical graduates from clinical research.

A recent report from the Institute of Medicine of the National Academy of Sciences has made a series of recommendations based on their assessment of both the state of clinical research and the training of health care professionals for future careers in clinical research. the report recommended the establishment of funding mechanisms for new clinical investigators, a recommitment to support General Clinical Research Centers (those components of AHC's around the country in which patient-focused research takes place), and commitment by the Medical Scientist Training Program to a widened focus, including population-based research along with careful tracking of the graduates of this program.

BIOMEDICAL RESEARCH POLICY AND THE FUTURE OF FUNDING

The environment of relative shrinking growth in available funds is likely to continue. In spite of limited resources, there will be expanded horizons for basic research and increased opportunities for clinical applications of basic research findings. In addition, there will unquestionably be new and important implications in the areas of economic, bioethical, and health policies. Some of these new policy implications will be based on research findings leading to the understanding of genetic control of biologic and pathologic processes. Many conclude that greater management flexibility will

be required for the NIH to respond to these rapid changes in health science and technology. Biomedical research funded by Federal dollars requires a delicate balance between the needs and expectations of the taxpayer who funds the research and researchers with increasingly sophisticated expertise who are best able to establish priorities for biomedical research.

III. Legislative History and Committee Action

The National Institutes of Health Revitalization Act of 1996, S. 1897, was introduced on June 21, 1996, by Senators Kassebaum, Kennedy, Jeffords, Pell, and Hatfield. The bill was referred to the Senate Committee on Labor and Human Resources.

The Senate Committee on Labor and Human Resources held hearings on the National Institutes of Health reauthorization on March 6 and 7, 1996, and May 7, 1996.

On Wednesday, July 1996, the committee held an executive session to consider S. 1897. Four amendments were adopted in executive session by voice vote, and S. 1897 was ordered to be reported favorably to the full Senate by a rollcall vote of 16 yeas.

AMENDMENTS ADOPTED BY VOICE VOTE DURING EXECUTIVE SESSION

Four amendments were adopted in executive session by voice vote.

1. Senator Wellstone offered an amendment to establish a program for the support of research and training with respect to Parkinson's disease by establishing the Morris K. Udall Awards for Innovation in Parkinson's disease research at up to ten centers.

2. Senators DeWine and Kennedy offered an amendment to establish within the Office of the Director of the NIH a Pediatric Research Initiative to increase pediatric biomedical research.

3. Senator Simon offered an amendment to increase the authorization level of diabetes-related research by 25 percent each year over the 3 years of the authorization. Senator Mikulski modified the amendment to provide for a 25-percent increase over 3 years.

4. Senator Frist offered an amendment to require the National Institutes of Health to prepare a report to the committee within 6 months of enactment of S.1897 explaining how it intends to implement the findings and recommendations of an earlier report to Congress entitled "Support For Bioengineering Research," submitted in August 1995.

AMENDMENT WITHDRAWN DURING EXECUTIVE SESSION

1. Senators Faircloth and Harkin offered an amendment to establish a National Center for Pain Research within the National Institutes of Health and 6 regional centers for pain research. The amendment proposed to improve the integration of pain-related research at the National Institutes of Health through a new organizational structure. Senator Kassebaum and others expressed concern about the administrative burden associated with the creation of new centers. The amendment was withdrawn by the sponsors with the understanding that work would continue in an attempt to develop an alternative proposal for a floor manager's amendment.

IV. COMMITTEE VIEWS

A. General overview of S. 1897

1. General

In crafting this legislation, the committee wrestled with the question: Should the Congress be directive and authorize more set-asides for specific diseases, or should it authorize institute funding that enables scientific discovery itself to determine the direction for research funding? In general, the committee tends toward the view that the latter is the better course: to make resources available to scientists to pursue new knowledge where it leads. The committee believes that this strategy has been highly productive in the National Institutes of Health's (NIH) assault on the diseases that afflict Americans.

2. Renewal of expiring authorities

GENERAL

This bill renews all expiring NIH authorities through fiscal year 1999. The committee recommends that institutes due for reauthorization be authorized at specific dollar amounts that have been increased to reflect biomedical research inflation. To determine the dollar amount to be authorized for 1997, the committee has used the Biomedical Research and Development Price Index (BRDPI) compounded over the 3 years since the last reauthorization. This results in an increase in the amount from 1994 to 1997 of approximately 11 percent. The out years are reauthorized at such sums as may be necessary.

On the other hand, the committee has taken the course of reauthorizing all other existing initiatives at such sums as may be necessary. The successful pursuit of science can rapidly change directions, particularly when breakthroughs point toward successful research strategies. This approach has the benefit of removing limits that exist over the duration of the reauthorization legislation so that funding can be determined annually by the appropriating process.

NATIONAL CANCER INSTITUTE

The progress that has been made in understanding the genetics of cancer has been gratifying. The discovery, for example, of the BRCA–1 gene that is linked to certain forms of breast cancer opens the door to a number of opportunities for screening and therapy. At the same time, it is recognized by the committee that each new discovery of this type introduces new social and ethical issues regarding the appropriate application of this new knowledge in a safe and reasoned way. The committee supports NCI's efforts to expand and intensify its activities with respect to cancer genetics and to coordinate its activities with other institutes and agencies with responsibilities in this area.

It is also clear to the committee that the broad understanding of the biology of cancers of one kind is likely to be valuable in the understanding of cancers of other organs. While the previously created special programs in breast cancer, cancer of the female repro-

ductive systems, and cancer of the prostate are all important programs, precise authorization amounts have not been set by the committee. Rather, funding levels will be determined through the annual appropriation process by Congress based on the success, and potential for success, of the science in these areas of research.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The committee is pleased to note the progressive decline in heart disease mortality in all segments of society. This is certainly the result of coordinated research efforts into the understanding of heart disease and its therapy. It is also comment on the use of public health approaches to prevention. Yet today cardiovascular diseases remain one of the leading causes of death in this country. Approximately one million deaths each year are directly related to cardiovascular diseases. Clearly, a continued research effort in this area is needed.

The committee is concerned about the increasing prevalence and severity of asthma in the United States. It is gratifying to see the application of patient education in asthma management techniques and their critical analysis. The demonstrated value of patient education and involvement in their own care superbly exemplifies how worthwhile it is to disseminate new knowledge gained from research directly to the patient for his or her personal benefit.

While the results of clinical studies have produced improvement in the survival of the many Americans who are born with, and spend a lifetime with, sickle cell disease, it is hoped that new applications of molecular medicine will yield even more fundamental techniques for the relief of suffering from this disease.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The reemergence of tuberculosis has presented a startling example of importance of NIH's ability to muster an agile response in the direction of research funding. With the various epidemiologic changes that occurred in the 1980's—such as immune suppression associated with HIV infection and new resistance to the usual antibiotics that treat tuberculosis—a new epidemic of tuberculosis emerged. The National Institute of Allergy and Infectious Diseases (NIAID) has made a substantial commitment to research on tuberculosis. Its program of incentives for new investigators to bring creative scientific thinking to the problems that have developed in the field of tuberculosis is a model for quick response to new imperatives in the study of disease, particularly emerging infections. The committee believes that the stabilization of the numbers of new cases of tuberculosis over the last 2 years demonstrates the ability of an energized infrastructure to respond to new health problems. It looks forward to even greater success in the reduction of this epidemic as basic research and clinical research come together for effective management of this complex health problem.

In past years, NIH has made very large investments in upgrading research facilities in response to public concerns about animal well-being and to diminish environmental factors that adversely affect research. However, the programs in Comparative Medicine which focus on animal-based research have been severely curtailed.

These programs address research in genetics, infectious diseases, cancer, diabetes and many other fields and should be strengthened.

3. Increasing administrative efficiency

GENERAL

During hearings before the committee, the Director of the NIH described additional efforts the agency is undertaking to streamline its research and administrative operations. The committee urges the Director to continue these efforts and remains committed to exploring mechanisms that will maximize the funds available for biomedical research.

MEETINGS OF ADVISORY COMMITTEES AND COUNCILS

The committee is aware that the advent of telecommunications technology, permitting more rapid resolution of committee and council business and other administrative efficiencies, now makes it unnecessary to mandate meeting at designated intervals. This provides an opportunity for resource savings afforded by scheduling meetings only as needed. Unneeded meetings are wasteful of resources, including time and effort on the part of council or committee members and staff, as well as travel expenses and compensation for members.

APPLICATION OF FEDERAL ADVISORY COMMITTEE ACT

It is the view of the committee that scientific and peer review groups are integral components of the NIH grant-making process. The function of these specialized peer review groups is very different than the public advisory rule envisioned at the inception of the Federal Advisory Committee Act (FACA). It is appropriate, therefore, to exempt scientific and peer review groups from the provisions of FACA and the associated administration burden. This does not exempt from the provisions of FACA the many other advisory committees and councils that serve the many roles and functions of the NIH.

ELIMINATION OR MODIFICATION OF REPORTS

It is the view of the committee that a number of reports required of the NIH by the Congress are sometimes duplicative and generally do not meet the intended goal of the original law that established their requirement. Under current law, the Director of the NIH and the directors of institutes and centers are required to provide administrative reports to the Secretary of Health and Human Services and Congress. There are now more effective mechanisms in place for communicating this information. Such mechanisms include publications (both printed and electronic), public testimony at the annual appropriations process and the triennial authorization process, as well as direct inquiry from members of the Congress.

It is the intention of the committee that elimination of these reports will improve the efficiency of the individual institutes and centers by allowing staff to concentrate on the administration of research programs, rather than on producing reports that are often untimely and no longer useful for the Congress.

INCREASED AMOUNT OF GRANTS THAT REQUIRE ONLY PEER REVIEW

Grant funding by the NIH is approved by a two-tier process. After approval by a peer review committee, grants than must be approved by the appropriate institute or center advisory council. It is the view of the committee that increasing from $50,000 to $100,000 the amount for grants that can be made after scientific and technical peer review eliminates duplication of the approval process beyond peer review for smaller grants and accelerates funding of new, cutting-edge proposals.

It is the view of the committee that this modification will streamline the workloads of the institutes, centers, and the National Library of Medicine, resulting in shortened time from review to award.

ELIMINATION OF CERTAIN ADVISORY BOARDS AND COMMITTEES

The committee is aware that current law establishes certain advisory committees, boards, and commissions that no longer carry out the purposes for which they were created. In every instance, the advisory committee, boards, and commissions listed below no duplicate responsibilities and authorities that are better carried out by other entities.

The functions of the National Diabetes Advisory Board, the National Digestive Disease Board, and the National Kidney and Urologic Diseases Advisory Board are adequately served by the National Diabetic and Digestive and Kidney Diseases Advisory Council. The purpose of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board is adequately served by the National Arthritis and Muscoloskeletal and Skin Diseases Advisory Council, as well as two interagency coordinating committees. The functions of the National Deafness and Other Communications Disorders Advisory Board overlap those served by the National Deafness and Other Communications Disorders Advisory Council. The National Commission on Alcoholism and Other Alcohol-Related Problems was activated briefly in 1980. Although funds were authorized, they were never appropriated, and it has remained inactive up to this time. The Advisory Council on Hazardous Substances Research and Training has completed its statutory mandate. Moreover, the functions of this council can be adequately served by the National Advisory Environmental Health Sciences Council.

Accordingly, the committee expects that the repeal of these boards and committees will be associated with appropriate savings that can be used more effectively for funding of research grants.

THE PAIN RESEARCH CONSORTIUM AT NIH

The Committee encourages the NIH Director to establish a Pain Research Consortium. The creation of a Pain Research Consortium would provide a forum for coordinating pain research activities, sharing information about research and related activities being conducted in the area of pain, developing ideas for collaborative research efforts, avoiding unnecessary duplication of research efforts, and thereby, achieving a more efficient use of Federal dollars. All NIH Institutes, Centers and Offices that are involved in pain research should be included as members of the Consortium. In addi-

tion, the NIH Pain Research Consortium should seek the opinions and advice from private organizations interested in pain research, as well as staff of other Federal agencies involved in studies of pain.

COORDINATION OF CHILD ABUSE AND NEGLECT RESEARCH

The committee recognizes that despite the magnitude and significance of the problem of child abuse and neglect, research in this field has not yet been organized into an integrated organized base of knowledge. To increase the viability of the work currently being done by NIH regarding child maltreatment, the committee believes it is essential that the child abuse and neglect portfolio at the NIH and its relevant Institutes be better coordinated and focused. As an important first step the committee strongly recommends that the NIH convene a working group made up of representatives of its component organizations currently supporting research on child maltreatment. The committee further encourages this working group to hold a conference on child abuse and neglect to assess the state-of-the-science and make recommendations for a research agenda in this field; including in this conference relevant outside organizations and recognized experts in child maltreatment.

4. National Human Genome Research Institute

The committee is aware of the importance of emerging knowledge of the human genome for the understanding of disease and its effective treatment. As we go into the next millennium, knowledge of genes and gene products will radically alter the physician's approach to disease. The committee expects that methods advanced by the National Center for Human Genome Research will continue to evolve and to influence many aspects of medical science long after the human genome has been sequenced. The committee hopes that the elevation of the National Center for Genome Research to institute status will ensure a continued focus of NIH resources on important genetic research.

The attention to ethical, social, and legal issues surrounding the genetic underpinnings of cancer and other diseases is a valuable investment. Therefore, the current 5 percent of extramural funds setaside for reviewing and funding proposals to address these issues is maintained in this institute's mission.

The additional authorities that accompany institute status will help to increase efficiency in this new institute. The committee expects that elevation of the center to institute status will have no additional budgetary ramifications and will require no additional full time employees.

5. Addressing the needs for expanded involvement in clinical research

GENERAL

The committee is aware that there are unprecedented pressures on academic health centers as a result of the health care market transformations. These pressures occur particularly in price-competitive health care markets where managed care plans have strong incentives to direct patients away form academic health cen-

ters to sources of care with lower costs. Moreover, because of reduced clinical incomes, the loss of clinical practice revenue has had the effect of reducing a substantial source of support for clinical research. The committee recognizes the attention that has been brought to the need for sustained, high-quality clinical research by studies performed by the Institute of Medicine of the National Academy of Sciences.

The committee is pleased that the leadership of the NIH has undertaken its own study of the ramifications of these changes upon clinical research by appointing a group of leading experts to a panel of clinical research. The committee believes that the panel on clinical research should produce, as soon as possible, specific recommendations that will increase attention and resources for the dilemma faced by academic health centers in their efforts to translate basic knowledge into clinical applications for patients. There is a particular interest by some members of the committee for the panel to evaluate what, if any, of the financial burden for clinical research should be assumed by managed care providers. The committee expects that the NIH will continue to monitor the effects of the ever-evolving market at regular intervals.

GENERAL CLINICAL RESEARCH CENTERS

The committee sees the General Clinical Research Centers as potential sources of solutions to some of the problems faced by academic health centers as they seek to maintain their academic missions in this changing economic environment. General Clinical Research Centers, widely distributed as they are around the country, draw on a broad range of research strengths from their parent academic institutions.

The committee expects to see increased interdisciplinary research in these settings, as well as greater usage of diverse settings for research such as ambulatory and even home settings that reduce costs compared to traditional inpatient research wards.

CLINICAL RESEARCH CAREER ENHANCEMENT AND INNOVATIVE MEDICAL SCIENCE AWARDS

The committee recognizes the importance of sustaining exemplary careers of expert clinical investigators and the importance of rewarding exceptional research ideas brought forward by clinical investigators at all stages of their careers. The committee intends that, with specific authorization of such awards, careers that might otherwise become fallow without adequate support will instead continue to develop creative solutions to the many health dilemmas that are currently unsolved.

It is the intention of the committee that only applications of exceptional merit will be funded. Only by maintaining such high standards can these awards be effective in sustaining valuable careers and leveraging creative new research concepts.

6. Education and training for clinical research

GENERAL

The committee is aware that an important resource for the future of clinical research is the training and education for the next

generation of investigators. The increasing costs of medical education have discouraged medical graduates for pursuing careers in clinical research because of the prolonged training that is required and the reduced incomes that are associated with such career preparation.

Nevertheless, there can be no shortcut to the excellence required for a career in patient-focused research. Consequently, even more creative strategies must be developed by the NIH to foster such training and careers.

RAISING LOAN REPAYMENT

To encourage qualified health professionals to pursue training in clinical research, the committee considers it appropriate to increase the maximum level of qualified student loans that could be repaid for participation in clinical research training fellowships at the NIH campus in Bethesda, MD. In addition, the venues should be expanded to include General Clinical Research Centers located throughout the country in academic health centers. In view of the periodic emergence of research fields, the committee would like to see greater flexibility available to the NIH to determine areas of research where loan repayment may be granted.

MEDICAL SCIENTIST TRAINING PROGRAM

The Medical Scientist Training Program is a highly successful program that has provided support for exceptionally qualified students to pursue the M.D. as well as a Ph.D. in a particular field that prepares the recipient for a career in biomedical research. This program can be the source of the future faculties of medicine and biomedical research institutions.

However, the fields in which the Ph.D. has been pursued have generally been the basic biologic sciences. On the other hand, the context of medicine and clinical research is changing dramatically. As managed care emerges as the dominant form of support for medical care, it becomes increasingly apparent that the sciences germane to population-focused research, as well as the economic components of care, must be part of the research training that is supported by Federal funds. The committee is aware that a study performed by the Institute of Medicine of the National Academy of Sciences has argued for broadening the fields wherein the Ph.D. may be obtained in the Medical Scientist Training Program. If the future faculties of medical schools are to prepare future physicians appropriately and soundly for their careers in medicine, those faculties must be composed of scholars in the broader fields of the population-based sciences, such as epidemiology, biostatistics, medical economics, and bioethics. However, it is the opinion of the committee that, while the NIH is best qualified to set the targets whereby these goals can be achieved, it has not been aggressive in encouraging grantees to pursue such a strategy.

The committee hopes that the NIH will closely track this program and be able to provide information in the future that may answer the following questions. What careers, in what disciplines, are pursued by previous recipients of support from this program? How many have pursued careers in the population-focused fields de-

scribed above? How successful is this program in retaining its graduates in academic careers?

7. National Fund for Health Research

The committee recognizes that the pressure is never-ending for increased funding for biomedical research created by expanding knowledge. Only one grant can be funded for every four applications approved by NIH peer-review groups. On the other hand, Federal support for the NIH must complete with the many other demands on the Federal budget.

The committee believes the importance of biomedical research is such that additional sources of funding must be assured. Accordingly, a National Fund for Health Research is established in the Department of the Treasury. This trust fund will be on budget. The committee believes that establishing such a fund is in itself an important first step toward assuring sustainable support for the essential mission of biomedical research.

B. Overview of substantive changes to S. 1897 contained in legislation adopted by the committee

1. Pediatric research initiative

The committee recognizes that developments in genetics and gene therapy are leading toward considerable growth in knowledge and opportunities in the prevention and treatment of diseases that affect children. Increased support for biomedical research at a fundamental level should lead to new treatments and cures for a variety of childhood diseases. Moreover, clinical effectiveness studies can potentially demonstrate how to improve the quality of care for children while reducing costs of care.

It is the intention of the committee that the resources provided by the pediatric research initiative will be allocated among NIH institutes by the Director of the NIH for extramural research in consultation with the institutes and any external advisers that the Director determines to be appropriate. The Director is encouraged to consider a central role for the National Institute of Child Health and Human Development in advising on the development of priorities and plans for allocation of funds. The Director should encourage trans-institute initiatives.

2. Diabetes research

The committee is encouraged by the success of biomedical research in recent years into causes and management of problems associated with diabetes mellitus. However, given the striking increase in the number of patients with diabetes, there continues to be a compelling need for a new advances in this field. Accordingly, the committee calls for increased funding in this field so as to encourage new and creative research applications.

It is anticipated that these funds would be applied wherever creative research is found. However, a coordinating and leadership role is recognized for both the National Institute of Diabetes and Digestive and Kidney Diseases and to the National Eye Institute in their initiatives directed specifically at this disease.

3. Parkinson's disease research

The committee is pleased to honor former Congressman Morris K. Udall, who was forced to end his 30-year service in the U.S. House of Representatives due to the disabling effects of Parkinson's disease. This amendment to S. 1897 is a modified form of a bill that has had bipartisan support by over half the Senate and a companion bill in the House that had similar broad-based support. It is intended to provide mechanisms to encourage expansion of the Federal Parkinson's research efforts in a speedy and effective way.

The committee notes that the NIH has undertaken active efforts to coordinate initiatives in this area, particularly as reflected by the 1995 Parkinson's Disease Research Planning Workshop. The coordination and collaboration efforts that have grown out of this workshop should be continued. The committee expects that new funding will be used to attract outstanding neuroscientists with innovative ideas to the field of Parkinson's disease research.

V. COST ESTIMATE

A letter form the Congressional Budget Office requested after committee action on July 17, 1996, has not been received to date, September 9, 1996. Due to time constraints, the CBO letter will appear in the Congressional Record at a later date, when it is received.

VI. REGULATORY IMPACT STATEMENT

The committee has determined that there will be no increase in the regulatory burden of paperwork as the result of this bill.

VII. SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Section 1 cites the act as the "National Institutes of Health Revitalization Act of 1996."

TITLE—PROVISIONS RELATING TO THE NATIONAL INSTITUTES OF HEALTH

Section 101. Director's discretionary fund

Section 101 amends section 402(i)(3) of the Public Health Service (PHS) Act by striking the authorized dollar amount and, instead, authorizes the Director's Discretionary Fund at such sums as may be necessary through fiscal year 1999.

Section 102. Children's vaccine initiative

Section 102 amends section 404B(c) of the PHS Act by striking the authorized dollar amount and, instead, authorizes the Children's Vaccine Initiative at such sums as may be necessary through fiscal year 1999.

TITLE II—PROVISIONS RELATING TO THE NATIONAL RESEARCH INSTITUTES

Section 201. Research on osteoporosis, Paget's disease, and related bone disorders

Section 201 amends section 409A(d) of the PHS Act by striking the authorized dollar amount and, instead, authorizes the programs related to research on osteoporosis, Paget's disease, and related bone disorders at such sums as may be necessary through fiscal year 1999.

Section 202. National Human Genome Research Institute

Section 202 amends part C of title IV of the PHS Act, adding a new subpart 18 which establishes the National Human Genome Research Institute. Its purpose is to characterize the structure and function of the human genome, including mapping and sequencing of individual genes. This purpose includes: (1) planning and coordinating the research goal of the genome project; (2) reviewing and funding research proposals; (3) conducting and supporting research training; (4) coordinating international genome research; (5) communicating advances in genome research to the public; (6) reviewing and funding proposals to address the ethical, legal, and social issues associated with the genome project (including legal issues regarding patents); and (7) planning and administering intramural, collaborative, and field research to study human genetic disease. It allows the director of the institute to conduct and support research training for which fellowship support is not provided under section 487 (National Research Service Awards) and is not residency training of physicians or other health professionals. It allows the director of the institute to make funding available at a level that is at least 5 percent of the total amount available for extramural research grants, for research in ethical, legal, and social issues with reference to genome research.

It transfers all functions, personnel, assets, liabilities, contracts, property, records, unexpended balances, authorizations, allocations, and other funds of the National Center of Human Genome Research to the new National Human Genome Research Institute. It transfers to the new institute and continues in effect all legal documents of the center. It deems that all previous references to the center in Federal law, executive order, rule, or any document shall refer to the new institute.

It authorizes the National Human Genome Research Institute at such sums as may be necessary through fiscal year 1999.

Section 203. Increased amount of grant and awards

Section 203 amends section 405(b)(2)(B) of the PHS Act by increasing from $50,000 to $100,000 the award amount that an institute can grant on the basis of technical or peer review alone, thereby increasing flexibility and saving the time and administrative cost required for advisory council approval for smaller grants.

Section 204. Meetings of advisory committees and councils

Section 204 amends section 406 of the PHS Act by eliminating required meeting schedules for advisory committees and councils.

Specifically, it eliminates the requirements for institute advisory councils to meet three times yearly, and for the National Cancer Advisory Board and the advisory council of the National Heart, Lung, and Blood Institute to meet four times yearly. It amends section 415(a)(3) of the PHS Act by eliminating the requirement for the President's Cancer Panel to meet four times a year.

It amends section 429(b) of the PHS Act by eliminating the requirement for the Institute of Diabetes and Digestive and Kidney Interagency Coordinating Committees to meet four times a year.

It amends section 439(b) of the PHS Act by eliminating the requirement for the Institute of Arthritis and Musculoskeletal and Skin Diseases Interagency Coordinating Committees to meet four times a year.

It amends section 464E(d) of the PHS Act by eliminating the requirement for the Institute on Deafness and Other Communication Disorders Interagency Coordinating Committees to meet four times a year

It amends section 464X(e) of the PHS Act by eliminating the requirement for the Institute of Nursing Research Advisory Council to meet three times a year.

It amends Part B of title IV of the PHS Act to create section 409B eliminating the application of the provisions of the Federal Advisory Committee Act (5 U.S.C. Ap. 2) to scientific and peer-review groups of the National Institutes of Health established under title IV.

Section 205. Elimination or modification of reports

Section 205 repeals section 403 of the PHS Act eliminating the biennial report of the Director of the National Institutes of Health to Congress and the President.

It repeals section 439(c) of the PHS Act eliminating the annual report of the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the annual report of the Skin Diseases Interagency Coordinating Committee.

It repeals section 442(j) of the PHS Act eliminating the annual report of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board.

It repeals section 494A(b) of the PHS Act eliminating the annual report of the Secretary of Health and Human Services on health services research relating to alcohol abuse and alcoholism, drug abuse, and mental health.

It repeals section 503(b) of the PHS Act eliminating the triennial report of the Secretary of Health and Human Services to Congress relating to alcoholism, alcohol abuse, and drug abuse.

It amends section 402(f)(3) changing the reporting requirement from annual to biennial for the report to the Director of the National Institutes of Health concerning prevention activities undertaken by the Associate Director for Prevention.

It repeals section 429(c) of the PHS Act eliminating the annual reports of the Coordinating Committees on Digestive Diseases, Diabetes Mellitus, and Kidney, Urologic, and Hematologic Diseases.

It repeals section 304 of the Home Health Care and Alzheimer's Disease Amendments of 1990 (42 U.S.C. 242q–3) eliminating the annual report of the Task Force on Aging.

It repeals subsections (b) and (c) of section 1122 of the PHS Act eliminating the annual reports related to sudden infant death syndrome.

It repeals subsection (h) of section 5 of the International Health Research Act of 1960 eliminating the annual report of the U.S.-Japan Cooperative Medical Science Program.

The bill instructs the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to report to the Congress on plans regarding how the findings of the report to Congress entitled "Support for Bioengineering Research," submitted in August 1995, will be implemented.

Conforming amendments

The bill amends section 404C(c) of the PHS Act making available a periodic revision of a plan regarding the use of animals for research to the Interagency Coordinating Committee on the Use of Animals in Research for inclusion in its minutes. This plan previously was provided to the Director of the National Institutes of Health for the biennial report of the Director.

The bill amends section 404E(d)(3)(B) of the PHS Act by eliminating the requirement for the submission of the biennial report of the Office of Alternative Medicine for inclusion in the biennial report of the Director of the National Institutes of Health. The director of the office will continue to prepare the biennial report.

The bill amends section 406(g) of the PHS Act by eliminating the need for advisory councils of the institutes to submit comments for inclusion in the biennial report of the Director of the National Institutes of Health.

The bill amends section 407 of the PHS Act by changing the section heading to "REPORTS" and eliminating the requirement for the director of each national research institute to submit a report for inclusion in the biennial report of the Director of the National Institutes of Health.

The bill amends section 416(b) of the PHS Act by eliminating the requirement for submission by the Associate Director for Prevention of the National Cancer Institute of the prevention activities of hat institute for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Associate Director for Prevention of the National Institutes of Health.

The bill strikes section 417(e) of the PHS Act, eliminating the submission of a report regarding the program in breast and gynecologic cancers for inclusion in the biennial report of the Director of the National Institutes of Health.

Teh bill amends section 423(b) of the PHS Act by eliminating the requirement for the report of the Associate Director for Prevention of the National Heart, Lung, and Blood Institute of the prevention activities of that institute for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Associate Director for Prevention of the National Institutes of Health.

The bill repeals section 433 of the PHS Act by eliminating a biennial report by the Director of the National Institute of Diabetes and Digestive and Kidney Diseases regarding diabetes and diges-

tive diseases research for inclusion in the biennial report of the Director of the National Institutes of Health.

The bill amends section 451(b) of the PHS Act by eliminating the requirement for the report of the Associate Director for Prevention of the National Institute of Child Health and Human Development of the prevention activities of that institute for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Associate Director for Prevention of the National Institutes of Health.

The bill amends section 452(d)(4) of the PHS Act by eliminating the submission of a report by the Director of the National Institute of Child Health and Human Development regarding the research plan for the National Center for Medical Rehabilitation Research for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Director.

The bill amends section 464I(b) of the PHS Act by eliminating the requirement for the report of the Associate Director for Prevention of the National Institute on Alcohol Abuse and Alcoholism of the prevention activities of the institute for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Associate Director for Prevention of the National Institutes of Health.

The bill amends section 464M(b) of the PHS Act by eliminating the requirement for a report of the Associate Director for Prevention of the National Institute on Drug Abuse of the prevention activities of that institute for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Associate Director for Prevention of the National Institutes of Health.

The bill amends section 464S(b) of the PHS Act by eliminating the requirement for a report of the Associate Director for Prevention of the National Institute of Mental Health of the prevention activities of that institute for inclusion in the biennial report of the Director of the National Institutes of Health. This report will be submitted directly to the Associate Director for Prevention of the National Institutes of Health.

The bill amends section 464X(g) of the PHS Act by eliminating the submission of a report from the advisory council of the National Institute of Mental Health regarding research plans for inclusion in the biennial report of the Director of the National Institutes of Health.

The bill amends section 464Y of the PHS Act by changing the section heading to "REPORTS" and eliminating the requirement for the Director of the National Institute of Mental Health to submit a report for inclusion in the biennial report of the Director of the National Institutes of Health.

The bill amends section 480(g) of the PHS Act by eliminating the requirement for the submission of a report from the advisory council of the National Center for Research Resources for inclusion in a biennial report of the director of the center.

The bill amends section 481 of the PHS Act by changing the section heading to "REPORTS" and eliminating the requirement for the Director of the National Center for Research Resources to sub-

mit a report for inclusion in the biennial report of the Director of the National Institutes of Health.

The bill amends section 486(d)(5)(B) by eliminating the submission of a report of the advisory committee of the Office of Women's Health for inclusion in the biennial report of the Director of the National Institutes of Health. The report of the committee is not, however, eliminated.

The bill amends section 486B(b) of the PHS Act by replacing the inclusion of the biennial report of the Director of the Office of Women's Health in the biennial report of the Director of the National Institutes of Health with submission directly to the Director of the National Institutes of Health.

The bill amends section 492B(f) of the PHS Act requiring the advisory council of each research institute to submit directly to the Director of the National Institutes of Health a report regarding the inclusion in clinical research of women and members of minority groups as subjects.

TITLE III—SPECIFIC INSTITUTES AND CENTERS

Subtitle A—National Cancer Institute

Section 301. Authorization of appropriations

Section 301 amends section 417B of the PHS Act in subsection (a) authorizing the National Cancer Institute at $3 billion in fiscal year 1997 and such sums as may be necessary for fiscal years 1998 and 1999. Subparagraph (b)(1)(A) is amended by striking the authorized dollar amount and, instead, authorizes programs in breast cancer basic research at such sums as may be necessary through fiscal year 1999. Subparagraph (b)(1)(B) is amended by striking the authorized dollar amount and, instead, authorizes programs in breast cancer clinical research, control programs, information and education programs, and research demonstration centers at such sums as may be necessary through fiscal year 1999. Paragraph (b)(2) is amended by striking the authorized dollar amount and, instead, authorizes research programs in ovarian cancer and other cancers of the female reproductive system at such sums as may be necessary through fiscal year 1999. Subsection (c) is amended by striking the authorized dollar amount and, instead, authorizes prostate cancer research programs at such sums as may be necessary through fiscal year 1999.

Section 302. DES study

Section 302 amends section 403A(e) of the PHS Act by striking the dollar amount and, instead, authorizes research and training programs related to conditions associated with exposure to the drug diethylstilbestrol at such sums as may be necessary through fiscal year 1999.

Subtitle B—National Heart, Lung, and Blood Institute

Section 311. Authorization of appropriations

Section 311 amends section 425 of the PHS Act by authorizing the National Heart, Lung, and Blood Institute at $1.5 billion in fis-

cal year 1997 and such sums as may be necessary for fiscal years 1998 and 1999.

Subtitle C—National Institute of Allergy and Infectious Diseases

Section 321. Research and research training regarding tuberculosis

Section 321 amends subpart 6 of part C of title IV in section 447(b) by striking the dollar amount and, instead, authorizes research and training programs related to tuberculosis at such sums as may be necessary through fiscal year 1999.

Section 322. Terry Beirn Community-Based AIDS Research Initiative

Section 322 amends section 2313(e) of the PHS Act by authorizing the Terry Beirn Community-Based AIDS Research Initiative at such sums as may be necessary through fiscal year 1999.

Subtitle D—National Institute of Child Health and Human Development

Section 331. Research centers for contraception and infertility

Section 331 amends section 452A(g) of the PHS Act by striking the dollar amount and, instead, authorizes these research centers at such sums as may be necessary through fiscal year 1999.

Subtitle E—National Institute on Aging

Section 341. Authorization of appropriations

Section 341 amends section 445I of the PHS Act by authorizing the National Institute on Aging at $550 million for fiscal year 1997, and such sums as may be necessary for fiscal years 1998 and 1999.

Subtitle F—National Institute on Alcohol Abuse and Alcoholism

Section 351. Authorization of appropriations

Section 351 amends section 464H(d)(1) of the PHS Act authorizing the National Institute on Alcohol Abuse and Alcoholism at $330 million for fiscal year 1997, and such sums as may be necessary for fiscal years 1998 and 1999.

Section 352. National Alcohol Research Center

Section 352 amends section 464J(b) of the PHS Act by eliminating a reference to a nonexistent section in health law [section 701(l)], and providing a definition of "construction" which had been inadvertently dropped in previous legislation. This definition is the long-used definition of "construction" that appeared, prior to elimination, in the PHS Act as amended through July 31, 1991.

Subtitle G—National Institute on Drug Abuse

Section 361. Authorization of appropriations

Section 361 amends section 464L(d)(1) of the PHS Act by authorizing the National Institute on Drug Abuse at $480 million for fiscal year 1997, and such sums as may be necessary for fiscal years 1998 and 1999.

Section 362. Medication development program

Section 362 amends section 464P(e) of the PHS Act by striking the dollar amount and, instead, authorizes the medication development program in the National Institute on Drug Abuse at such sums as may be necessary through fiscal year 1999.

Section 363. Drug abuse research centers

Section 363 amends section 464N(b) of the PHS Act by eliminating a reference to a nonexistent section in health law [section 701(l)] and providing a definition of "construction" which had been inadvertently dropped in previous legislation. This definition is the long-used definition of "construction" that appeared, prior to elimination, in the PHS Act as amended through July 31, 1991.

Subtitle H—National Institute of Mental Health

Section 371. Authorization of appropriations

Section 371 amends section 464R(f)(1) of the PHS Act by authorizing the National Institute of Mental Health at $750 million in fiscal year 1997 and such as may be necessary for fiscal years 1998 and 1999.

Subtitle I—National Center for Research Resources

Section 381. Authorization of appropriations

Section 381 amends section 481A(h) and 481B(a) of the PHS Act by striking the dollar amount and, instead, authorizes funds that may be reserved for construction of regional primate centers at such sums as may be necessary through 1999.

Section 382. General Clinical Research Centers

Section 382 amends part B of title IV of the PHS Act adding a new section, 409C, General Clinical Research Centers. Subsection (a) establishes in law General Clinical Research Centers, entities that already exist in academic medical centers throughout the United States. These centers are to support clinical studies and clinical research career development in these settings. Subsection (b) expands the activities of clinical research centers by the use of telecommunications and telemedicine initiatives. Subsection (c) authorizes, for the purpose of making grants under subsection (a), such sums as may be necessary through fiscal year 1999.

Section 383. Enhancement Awards

Section 383 amends part B of title IV of the PHS Act by adding a new section, 409D, Enhancement Awards. Subsection (a) establishes clinical research career enhancement awards to support individual careers in clinical research. Applications for these awards will be made by individual scientists. They will not exceed $130,000 per year per grant and will be for terms of 5 years. Up to 20 new awards will be made in each of the first 2 fiscal years that these grants are made. It authorizes the clinical research career enhancement awards program at such sums as may be necessary for each of the fiscal years 1997 through 1999.

Subsection (b) establishes innovative medical science awards to support individual clinical research projects. Applications for these awards will be made by individual scientists. They will not exceed $100,000 per year per grant. It authorizes innovative medical science awards at such sums as may be necessary for each of the fiscal years 1997 through 1999.

Subsection (c) instructs the Director of the National Institutes of Health, in cooperation with the Director of the National Center for Research Resources, to establish peer review mechanisms which include individuals who are exceptionally qualified to appraise the merits of clinical research to evaluate applications for clinical research fellowships, clinical research career enhancement awards, and innovative medical science awards.

Section 384. Waiver of limitations

Section 384 amends section 481A of the PHS Act by making modifications in the support for modernization and construction of biomedical and behavioral research facilities. Subsection (b)(3)(A) enlarges the membership of the Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities from 9 to 12 members. Subparagraph (e)(1)(A) reduces the percentage of support provided by this funding mechanism for the modernization and construction of such research facilities from 50 percent to 40 percent. Subparagraph (e)(1)(B) reduces the percentage of support provided by this funding mechanism for the modernization and construction of multipurpose facilities from 40 percent to 30 percent of the necessary cost of such construction that the Director determines to be proportionate to the contemplated use of such a facility.

Paragraph (e)(4) allows the limitations described in subparagraph (e)(1)(A) and (e)(1)(B) to be waived at the discretion of the Director.

Subsection (h) is amended by striking the authorized dollar amount and, instead, authorizes the program for modernization and construction of research facilities at such sums as may be necessary for each of the fiscal years 1997 through 1999.

Subtitle J—National Library of Medicine

Section 391. Authorization of appropriations

Section 391 amends section 486(a) of the PHS Act by authorizing the National Library of Medicine at $160 million in fiscal year 1997 and such sums as may be necessary for fiscal years 1998 and 1999.

Section 392. Increasing the cap on grant amounts

Section 392 amends section 474(b)(2) of the PHS Act increasing the cap on grants to medical libraries from $1 million to $1.25 million per year.

TITLE IV—AWARDS AND TRAINING

Section 401. Medical Scientist Training Program

Section 401 instructs the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to expand the Medical Scientist Training Program to in-

clude opportunities to pursue the Ph.D. degree in fields that will contribute to training clinical investigators in the skills necessary for performing patient-oriented clinical research. It instructs the Director to designate specific percentages for such disciplines as economics, epidemiology, public health, bioengineering, biostatistics, and bioethics.

Section 402. Raise in maximum level of loan repayments

Section 402(a) amends subsection 487A(a) of the PHS Act by increasing from $20,000 to $35,000 the amount of educational loans that can be repaid by the Federal Government for each year that a qualified health professional spends as an employee of the National Institutes of Health performing research on Acquired Immune Deficiency Syndrome. It amends subsection (b) by authorizing the loan repayment program for research with respect to AIDS at such sums as may be necessary through fiscal year 1999.

The bill amends subsection 487B(a) of the PHS Act by increasing from $20,000 to $35,000 the amount of educational loans that can be repaid by the Federal Government for each year that a qualified health professional spends conducting research with respect to contraception and infertility.

The bill amends paragraph 487C(a)(1) of the PHS Act by increasing from $20,000 to $35,000 the amount of educational loans that can be repaid by the Federal Government for each year that a qualified health professional spends as an employee of the National Institutes of Health conducting research without limitation as to the subject of that research.

The bill amends paragraph 487E(a)(1) of the PHS Act by increasing from $20,000 to $35,000 the amount of educational loans that can be repaid by the Federal Government for each year that a qualified health professional from a disadvantaged background spends as an employee of the National Institutes of Health conducting clinical research. It amends paragraph 487E(a)(3) of the PHS Act to allow the National Institutes of Health to offer participants in the clinical research loan repayment program from disadvantaged backgrounds the same tax reimbursement benefits provided in the National Health Service Corps Loan Repayment Program.

Section 403. General loan repayment program

Section 403 amends part G of title IV of the PHS Act by adding a new section, 487F, General Loan Repayment Program. It allows the National Institutes of Health to offer participants $35,000 in educational loan repayment by the Federal Government for each year of participation in this program. The Director will identify annually the areas of research for which loan repayments can be made. Such loan repayment agreements shall be for a minimum of 2 years.

Subsection (b) provides to participants in the General Loan Repayment Program the same provisions that apply to the National Health Service Corps Loan Repayment Program.

Subsection (c) authorizes the General Loan Repayment Program at such sums as may be necessary for each of the fiscal years 1997 through 1999.

Section 404. Clinical research assistance

Section 404 amends section 487(a)(1)(C) of the PHS Act by increasing the number of loan repayment contracts for individuals from disadvantaged backgrounds from 50 to 100 individuals during each fiscal year through 1999.

It amends section 487E of the PHS Act by striking from the section heading "FROM DISADVANTAGED BACKGROUNDS." It amends subsection 487E(a)(1) of the PHS Act to eliminate reference to health professionals who are from disadvantaged backgrounds. Paragraph 487E(a)(2) ensures that not less than 50 percent of the amounts used in this section are for qualified health professionals from disadvantaged backgrounds. Subsection 487E(c) expands the positions considered as clinical research training positions to include service in a General Clinical Research Center or other organization and institution determined to be appropriate by the Director of the National Institutes of Health. Subsection 487(d) authorizes this loan repayment program for clinical researchers at such sums as may be necessary for each fiscal year.

TITLE V—RESEARCH WITH RESPECT TO AIDS

Section 501. Comprehensive plan for expenditure of AIDS appropriations

Section 501 amends paragraph 2353(d)(1) of the PHS Act by authorizing the comprehensive plan for expenditure of AIDS appropriations through fiscal year 1999.

Section 502. Emergency AIDS discretionary fund

Section 502 amends paragraph 2356(g)(1) of the PHS Act by striking the authorized dollar amount and, instead, authorizes the emergency AIDS discretionary fund at such sums as may be necessary for each of the fiscal years 1997 through 1999.

TITLE VI—GENERAL PROVISIONS

Subtitle A—Authority of the Director of the NIH

Section 601. Authority of the Director of the NIH

Section 601 amends section 402(b) of the PHS Act to expand the authorities of the Director of the NIH. Paragraph 402(b)(13) of the PHS Act expands the authority of the Director to conduct and support research training. Paragraph 402(b)(14) of the PHS Act expands the authority of the Director to appoint health care professionals subject to the provisions of title 5 of the United States Code (U.S.C.), relating to appointments and classifications in the competitive service and their compensation subject to provisions of chapter 74 title 38, U.S.C.

Subtitle B—Office for Rare Disease Research

Section 611. Establishment of Office of Rare Disease Research

Section 611 amends part A of title IV of the PHS Act by adding a new section, 404F, Office for Rare Disease Research. Subsection (a) establishes in law the Office for Rare Disease Research within the Office of the Director of the NIH. It is to be headed by a Direc-

tor who shall be appointed by the Director of the NIH. Subsection (b) establishes the purpose of the office to promote and coordinate research on rare diseases through a strategic research plan and to establish and manage a clinical research database. Subsection (c) establishes an advisory council for the purpose of providing advice to the director of the office. Subsection (d) establishes the duties of the director of the office. These duties include: (1) develop a comprehensive plan for the conduct and support of research on rare diseases: (2) coordinate and disseminate information on rare diseases among the institutes and the public; (3) support research training and encourage the participation of a diversity of individuals in the conduct of rare disease research; (4) identify projects or research of rare diseases that should be conducted or supported by the NIH; (5) develop and maintain a central database on current government-sponsored clinical research projects for rare diseases; (6) determine the need for registries of research subjects and epidemiologic studies of rare disease populations; and (7) prepare biennial reports on the activities carried out by the office for the Secretary and the Congress.

Subtitle C—Certain Reauthorization

Section 621. National Research Service Awards

Section 621 amends section 487(d) of the PHS Act by striking the authorized dollar amount and, instead, authorizes the national research service awards program at such sums as may be necessary for each of the fiscal years 1997 through 1999.

Section 622. National Foundation for Biomedical Research

Section 622 amends section 499(m)(1) of the PHS Act by authorizing the National Foundation for Biomedical Research at such sums as may be necessary for each of the fiscal years 1997 through 1999.

Subtitle D—Miscellaneous Provisions

Section 631. Establishment of National Fund for Health Research

Section 631 amends part A of title IV of the PHS Act by adding a new section, 404G, Establishment of National Fund for Health Research. Subsection (a) establishes in the U.S. Department of the Treasury a fund to be known as the National Fund for Health Research to consist of amounts that may be transferred to that fund as well as interest earned on the investment of amounts in the fund. Subsection (b) provides that the Secretary shall distribute all amounts in the fund to research institutes and centers in the same proportions as the amounts appropriated to that institute or center relative to the total amount appropriated for the entire NIH for the fiscal year. It further provides that no expenditure shall be made from the fund in a fiscal year that the annual appropriated amount for the NIH is less than the previous fiscal year. A source of revenue for the fund is not provided.

Section 632. Definition of clinical research

Section 632 amends part A of title IV of the PHS Act by adding a new section, 404H, Definition of Clinical Research. It establishes that the term "clinical research" means patient-oriented clinical research conducted with human subjects; or research on the causes and consequences of disease in human populations; or research on material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting, to clarify a problem in human physiology, pathophysiology or disease, epidemiologic or behavioral studies, outcomes research, or health services research.

Section 633. Senior Biomedical Research Service

Section 633 amends section 228 of the PHS Act by adding a new subsection (h) which establishes that the Secretary shall be treated as a nonprofit entity for the entity for the purposes of making contributions to the retirement systems of appointees under the Senior Biomedical Research Service. This is done to permit such appointees to continue to be covered fully under the retirement systems of which they were members immediately prior to their appointment.

Section 634. Establishment of a Pediatric Research Initiative

Section 634 amends part A of title IV of the PHS Act by adding a new section, 404I, Pediatric Research Initiative. Subsection (a) establishes within the Office of Director of the NIH a pediatric research initiative under the leadership of the Director. Subsection (b) establishes the purpose of the initiative. It includes: (1) increased support for pediatric biomedical research within the NIH to ensure that the expanding opportunities for advancement in scientific investigations and care for children are realized; (2) enhanced collaborative efforts among the institutes to support multidisciplinary research in the areas that the Director deems most promising; (3) increased support for pediatric outcomes and medical effectiveness research; (4) the development of adequate pediatric clinical trials and pediatric use information to promote safer and more effective use of prescription drugs in the pediatric population; and (5) recognition of the special attention pediatric research deserves. Subsection (c) establishes the duties of the Director in this capacity which include: (1) consultation with the institutes and appropriate advisers when considering the role of the Institute for Child Health and Human Development; (2) allocating, with broad discretion, initiative assistance among the institutes, among types of grants, and between basic and clinical research as long as the assistance is directly related to pediatric illnesses and the assistance is extramural; and (3) oversight of any newly appropriated initiative funds and accountability for their expenditure to Congress and the public. Subsection (d) authorizes the pediatric initiative at $50 million over fiscal years 1997 through 1999.

Section 635. Diabetes research

Section 635 authorizes conduct and support of diabetes-related research by the NIH at the amount appropriated for fiscal year

1996 for each of the fiscal years 1997 through 1999, plus an additional 25 percent of the amount appropriated for fiscal year 1996 over the ensuing 3 fiscal years through fiscal year 1999.

Section 636. Parkinson's research

Section 636 amends part B of title IV of the PHS Act by adding a new section, 409E, Parkinson's Disease. Subsection (a) establishes a program for the conduct and support of research and training with respect to Parkinson's disease. Subsection (b) establishes the role of this program in interinstitute coordination and provides for the convening of a research planning conference every 2 years from which there will be a report to Congress.

Subsection (c) establishes up to 10 Morris K. Udall Centers for Research on Parkinson's Disease that will be funded by core center grants. These centers will use the facilities of a single institution or consortium of institutions to conduct basic and clinical research. They may conduct training, programs for continuing education of health professionals, programs for dissemination of information to the public, and develop brain banks for the collection of specimens related to Parkinson's disease. Separately, or in collaboration with other centers, they will establish a nationwide data system derived from patient populations with Parkinson's disease, establish a Parkinson's Disease Information Clearinghouse, and establish a national education program that fosters a national focus on Parkinson's disease. The bill establishes that Udall Centers may use center funds to provide stipends for scientists and health professionals enrolled in training programs. The bill provides that Centers will be supported for periods of 5 years, renewable for 5-year periods after peer review.

Subsection (d) establishes the Morris K. Udall Awards for Innovation in Parkinson's Disease Research to support outstanding neuroscientists and clinicians who bring innovative ideas to bear on the understanding of the pathogenesis, diagnosis, and treatment of Parkinson's disease.

Subsection (e) authorizes the Parkinson's disease research program at $80 million for fiscal year 1997 and such sums as may be necessary for fiscal years 1998 and 1999.

Subtitle E—Repeals and Conforming Amendments

Section 641. Repeals and conforming amendments

Section 641(a) amends section 403(5) of the PHS Act by replacing the designation "Division of Research Resources" with "National Center for Research Resources" so as to cite the correct designation for this center. It amends sections 403(5) and 408(a)(2) of the PHS Act by replacing the designation "National Center for Nursing Research" with "National Institute of Nursing Research" so as to cite the correct designation for this institute. It amends sections 406(b)(2)(A), 406(h)(2)(A)(v), 424(c)(3)(B)(v), 424(c)(3)(B)(x), 429(b), 430(b)(2)(A)(I), 439(b), 452(f)(3)(B)(xi), 466(a)(1)(B), and 480(b)(2)(A) of the PHS Act by replacing the designation "Chief Medical Director of the Department of Veterans Affairs" with "Under Secretary for Health of the Department of Veterans Affairs" so as to cite the correct designation for this position.

Section 641(b) amends section 406(h) of the PHS Act to provide for greater flexibility in the governance of advisory councils.

Section 641(c) repeals section 430 of the PHS Act eliminating the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board.

Section 641(d) repeals section 442 of the PHS Act eliminating the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board.

Section 641(e) amends subpart 6 of part C of title IV of the PHS Act by redesignating section 447 as section 447A.

Section 641(f) repeals section 464D of the PHS Act eliminating the National Institute on Deafness and Other Communication Disorders Advisory Board.

Section 641(g) amends section 489 of the PHS Act by eliminating a requirement that the National Academy of Sciences be used to conduct continuing studies with respect to biomedical and behavioral research personnel.

Section 641(h) repeals section 18 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Amendments of 1979 (42 U.S.C. 4541 note) eliminating the National Commission on Alcoholism and Other Alcohol-Related Problems.

Section 641(i) amends section 311(a) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (42 U.S.C. 9660(a) eliminating the Advisory Council on Hazardous Substances Research and Training.

VIII. ADDITIONAL VIEWS OF SENATORS COATS, DEWINE, FAIRCLOTH, GREGG, AND ASHCROFT

This bill goes far toward supporting, continuing, and revitalizing the essential work of the National Institutes of Health and we are pleased to have supported its passage.

However, we are concerned that the bill fails to address serious issues regarding the use of Federal funds made available through programs authorized by this bill to experiment on human embryos and fetuses—unborn children—some of them living at the time of the research; others made available by induced abortion.

Data from the National Institutes of Health confirms that substantial Federal funds—millions of dollars—are spent on research using human fetuses. We are alarmed by such experimentation on these humans in these circumstances. We suggest that the public is not well served when taxpayer funds are used for research that is opposed by millions and millions of Americans as fundamentally unethical. We question whether medical science is best advanced by using scarce research funds in this way when acceptable alternative therapies and sources of tissue might more productively be explored.

JOHN ASHCROFT.
DAN COATS.
LAUCH FAIRCLOTH.
MIKE DEWINE.
JUDD GREGG.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

* * * * * * *

NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1996

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PUBLIC HEALTH SERVICE ACT

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SEC. 402(i)(3) For the purpose of carrying out this subsection, there are authorized to be appropriated [$25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

* * * * * * *

SEC. 404B(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section [$20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

* * * * * * *

SEC. 409A(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated [$40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

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TITLE IV, PART C

* * * * * * *

Subpart 18—National Human Genome Research Institute

SEC. 464Z. PURPOSE OF THE INSTITUTE.

(a) IN GENERAL.—The general purpose of the National Human Genome Research Institute is to characterize the structure and func-

tion of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

(1) planning and coordinating the research goal of the genome project;

(2) reviewing and funding research proposals;

(3) conducting and supporting research training;

(4) coordinating international genome research;

(5) communicating advances in genome science to the public;

(6) reviewing and funding proposals to address the ethical, legal, and social issues associated with the genome project (including legal issues regarding patents); and

(7) planning and administering intramural, collaborative, and field research to study human genetic disease.

(b) RESEARCH.—The Director of the Institute may conduct and support research training—

(1) for which fellowship support is not provided under section 487; and

(2) that is not residency training of physicians or other health professionals.

(c) ETHICAL, LEGAL, AND SOCIAL ISSUES.—

(1) IN GENERAL.—Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Institute shall make available not less than 5 percent of amounts made available for extramural research for carrying out paragraph (6) of such subsection.

(2) NONAPPLICATION.—With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Institute certifies to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.

(d) TRANSFER.—

(1) IN GENERAL.—There are transferred to the National Human Genome Research Institute all functions which the National Center for Human Genome Research exercised before the date of enactment of this subpart, including all related functions of any officer or employee of the National Center for Human Genome Research. The personnel employed in connection with, and the assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds employed, used, held, arising from, available to, or to be made available in connection with the functions transferred under this subsection shall be transferred to the national Human Genome Research Institute.

(2) LEGAL DOCUMENTS.—All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, regulations, privileges, and other administrative actions which have been issued, made, granted, or allowed to become effective in the performance of functions which are transferred under this subsection shall continue in effect according

to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law.

(3) REFERENCES.—References in any other Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or relating to the National Center for Human Genome Research shall be deemed to refer to the National Human Genome Research Institute.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 1997 through 1999.

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SEC. 401(b)(1) * * *

* * * * * * *

(R) The National Human Genome Research Institute.

(2) [(D) The National Center for Human Genome Research.]

[(E)] *(D)* The Office of Dietary Supplements.

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TITLE IV, PART E, SUBPART 3

[(a) The general purpose of the National Center for Human Genome Research (in this subpart referred to as the "Center") is to characterize the structure function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

[(1) planning and coordinating the research goal of the genome project;

[(2) reviewing and funding research proposals;

[(3) developing training programs;

[(4) coordinating international genome research;

[(5) communicating advances in genome science to the public; and

[(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project (including legal issues regarding patents).

[(b) The Director of the Center may conduct and support research training—

[(1) for which fellowship support is not provided under section 487; and

[(2) that is not residency training of physicians or other health professionals.

[(c)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Center shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

[(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Center certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has

determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.**]**

* * * * * * *

SEC. 405(b)(2)(B)(i) if the direct cost of the grant or cooperative agreement to be made does not exceed **[**$50,000**]** *$100,000*, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds **[**$50,000**]** *$100,000*, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved; and

* * * * * * *

SEC. 406(e) MEETINGS.—The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established **[**, but at least three times each fiscal year**]**. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

* * * * * * *

(h)(2)(A)(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years; *and*

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy (or the designees of such officers) **[**; and**]**.

[(vi) the Board shall meet at least four times each fiscal year.**]**

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(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute**[**, except that the advisory council shall meet at least four times each fiscal year**]**.

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SEC. 415(a)(3) The Panel shall meet at the call of the chairman**[**, but not less often than four times a year**]**. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

* * * * * * *

SEC. 429(b) MEMBERSHIP; CHAIRMAN; MEETINGS.—Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Chief medical Director of the Veterans' Administration (Under Secretary for Health of the Department of Veterans Affairs), and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman **[**, but not less often than four times a year**]**.

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SEC. 439(b) MEMBERSHIP; CHAIRMAN; MEETINGS.—Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Department of Veterans Affairs (Under Secretary for Health of the Department of Veterans Affairs), and the Assistant Secretary of Defense for Health affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman **[**, but not less often than four times a year**]**.

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SEC. 464E(d) CHAIRMAN; MEETINGS.—The Coordinating Committee shall be chaired by the Director of NIH (or the designee of the Director). The Committee shall meet at the call of the chair **[**, but not less often than four times a year**]**.

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SEC. 464X(e) MEETINGS.—The advisory council shall meet at the call of the chairman or upon the request of the Director of the Institute **[**, but at least three times each fiscal year**]**. The location of the meetings of the advisory council is subject to the approval of the Director of the Institute.

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SEC. 480(e) MEETINGS.—The advisory council shall meet at the call of the chairman or upon the request of the Director of the Center **[**, but at least three times each fiscal year}. The location of the meetings of the advisory council is subject to the approval of the Director of the Center.

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TITLE IV, PART B

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SEC. 409B. APPLICATION OF FEDERAL ADVISORY COMMITTEE ACT.

Notwithstanding any other provision of law, the provisions of the Federal Advisory Committee At (5 U.S.C. Ap. 2) shall not apply to a scientific or technical peer review group, established under this title.

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[SEC. 403. BIENNIAL REPORT OF DIRECTOR TO PRESIDENT AND CONGRESS; CONTENTS.

[The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

[(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

[(2) a description of the activities undertaken to improve grants and contracting accountability and technical and scientific peer review procedures of the National Institutes of Health and the national research institutes;

[(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared;

[(4) a description of the health related behavioral research that has been supported by the National Institutes of Health in the preceding 2-year period, and a description of any plans for future activity in such area; and

[(5) the biennial reports of the Directors of each of the national research institutes, the Director of the Division of Research Resources, and the Director of the National Center for Nursing Research.

The first report under this section shall be submitted not later than July 1, 1986, and shall relate to the fiscal year ending September 30, 1985. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.]

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SEC. 439 [(c) ANNUAL REPORT.—Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a).]

* * * * * * *

SEC. 442 [(j) ANNUAL REPORT.—The Advisory Board shall prepare an annual report for the Secretary which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

[(3) summaries and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made;

[(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a); and

[(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculosketal diseases.]

* * * * * * *

SEC. 494A [(b) REPORT.—Not later than December 30, 1993, and each December 30 thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report concerning the activities carried out with the amounts referred to in subsection (a).]

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SEC. 503 [(b) DRUG ABUSE.—The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

[(1) describing the health consequences and extent of drug abuse in the United States;

[(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

[(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.]

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SEC. 402(f)(3) [annually] *biennially* prepare and submit to the Director of NIH a report concerning the prevention and dissemination activities undertaken by the Associate Director, including—

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SEC. 429 [(c) ANNUAL REPORT.—Each Committee shall prepare an annual report for—

[(1) the Secretary;

[(2) the Director of NIH; and

[(3) the Advisory Board established under section 430 for the diseases for which the Committee was established, detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.]

* * * * * * *

[Sec. 304(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act (Nov. 15, 1990), and annually thereafter, the Task Force shall prepare and submit to the Secretary, and to the Committee on Energy and Commerce of the House of

Representatives and the Committee on Labor and Human Resources of the Senate, a report providing the recommendations required in section 301(b).

[(b) AVAILABILITY TO PUBLIC.—The Task Force may make available to the public copies of the reports required in subsection (a).]

* * * * * * *

SEC. 1122. [SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS.]

(a) Adequate amounts for identification and prevention progress. From the sums appropriated to the National Institute of Child Health and Human Development, the Secretary shall assure that there are applied to research [of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate,], *such amounts each year as will be adequate for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, and to the relationship of the high-risk pregnancy and high-risk infancy research to sudden infant death syndrome,* given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.

[(b) Reports to Congressional committees; contents; data as to applications and funds for specific and general research, summary of findings and plan for advantage of research leads and findings.

[(1) Not later than ninety days after the close of the fiscal year ending September 30, 1979, and of each fiscal year thereafter, the Secretary shall report to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives specific information for such fiscal year on—

[(A) the (i) number of applications approved by the Secretary in the fiscal year reported on for grants and contracts under this Act for research which relates specifically to sudden infant death syndrome, (ii) total amount requested under such applications, (iii) number of such applications for which funds were provided in such fiscal year, and (iv) total amount of such funds; and

[(B) the (i) number of applications approved by the Secretary in such fiscal year for grants and contracts under this Act for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, (ii) relationship of the high-risk pregnancy and high-risk infancy research to sudden infant death syndrome, (iii) total amount requested under such applications, (iv) number of such applications for which funds were provided in such fiscal year, and (v) total amount of such funds.

[(2) Each report submitted under paragraph (1) of this subsection shall—

[(A) contain a summary of the findings of intramural and extramural research supported by the National Institute of Child Health and Human Development relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of such paragraph (1), and the plan of such Institute for taking maximum advantage of such research leads and findings; and

[(B) provide an estimate of the need for additional funds over each of the next five fiscal years for grants and contracts under this Act for research activities described in such subparagraphs.

[(c) Reports to Congressional Committees, current and past estimates for research. Within five days after the Budget is transmitted by the President to the Congress for each fiscal year after fiscal year 1980, the Secretary shall transmit to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives an estimate of the amounts requested for the National Institute of Child Health and Human Development and any other Institutes of the National Institutes of Health, respectively, for research relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of subsection (b)(1) of this section, and a comparison of such amounts with the amounts requested for the preceding fiscal year.]

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INTERNATIONAL HEALTH RESEARCH ACT OF 1960

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SEC. 5. AUTHORITY OF PRESIDENT.

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[(h) REPORT TO CONGRESS.—

[The President shall transmit to the Congress at the beginning of each regular session, a report summarizing activities under this section and making such recommendations as he may deem appropriate.]

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PUBLIC HEALTH SERVICE ACT

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TITLE IV

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SEC. 404C(c) REVISIONS OF PLAN.—The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be [included in the first biennial report under section 403 that is submitted after the revision if made.] *made available to the committee established under subsection (e) and included in the official minutes of the committee.*

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SEC. 404E(d)(3)(B) submit each such report to the Director of NIH [for inclusion in the biennial report under section 403].

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SEC. 406(g) COMMENTS AND RECOMMENDATIONS FOR INCLUSION IN BIENNIAL REPORT; ADDITIONAL REPORTS.—Each advisory council may prepare, [for inclusion in the biennial report made under section 407] *as it may determine appropriate,* (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. [Each advisory council may prepare such additional reports as it may determine appropriate.]

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SEC. 407. [BIENNIAL REPORT] *REPORTS.*

The Director of each national research institute, after consultation with the advisory council for the institute, [shall prepare for inclusion in the biennial report made under section 403 a biennial] *may prepare* a report which shall consist of a description of the activities of the institute and program policies of the Director of the institute in the fiscal years respecting which the report is prepared. The Director of each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).

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SEC. 416(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section [407] *402(f)(3)* a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

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SEC. 417 [(e) REPORT.—The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 407, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

[(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

[(2) an assessment of the development, revision, and implementation of such plan;

[(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancers and cancers of the reproductive system of women;

[(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system

of women conducted and supported by the National Institutes of Health; and

[(5) such comments and recommendations as the Director considers appropriate.]

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SEC. 423(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section [407] *402(f)(3)* a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

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[SEC. 433. BIENNIAL REPORT.

[The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

[(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

[(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976

[The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431].

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SEC. 451(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section [407] *402(f)(3)* a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

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SEC. 452(d)(3) [(A) Not] *Not* later than 18 months after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, the Director of the Institute shall transmit the Research Plan to the Director of NIH, who shall submit the Plan to the President and the Congress.

[(B) Subparagraph (a) shall be carried out independently of the process of reporting that is required in sections 403 and 407.]

(4) The Director of the Institute shall periodically revise and update the Research Plan as appropriate, after consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f). A description of any revisions in the Research Plan shall be [contained in each report prepared under section 407 by the Director of the Institute.] *transmitted to the Director of NIH.*

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SEC. 4641(b) BIENNIAL REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section [407] *402(f)(3)* a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

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SEC. 464S(b) REPORT.—The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section [407] *402(f)(3)* a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

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SEC. 464X(g) MATERIALS FOR INCLUSION IN THE BIENNIAL REPORT; ADDITIONAL REPORTS.—The advisory council may prepare, [for inclusion in the biennial report made under section 464Y] *as it may determine appropriate,* (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. [The advisory council may prepare such additional reports as it may determine appropriate.]

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SEC. 464Y. [BIENNIAL REPORT] REPORTS.

The Director of the Institute after consultation with the advisory council for the Institute, [shall prepare for inclusion in the biennial report made under section 403 a biennial] *may prepare a* report which shall consist of a description of the activities of the Institute and program policies of the Director of the Institute in the fiscal years respecting which the report is prepared. The Director of the Institute may prepare such additional reports as the Director determines appropriate. The Director of the Institute shall provide the advisory council of the Institute an opportunity for the submission of the written comments referred to in section 464X(g).

* * * * * * *

SEC. 480(g) MATERIAL FOR INCLUSION IN BIENNIAL REPORT; ADDITIONAL REPORTS.

The advisory council may prepare, [for inclusion in the biennial report made under section 481] *as it may determine appropriate,* (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Center in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Center. [The advisory council may prepare such additional reports as it may determine appropriate.]

* * * * * * *

SEC. 481. [BIENNIAL REPORT] *REPORTS.*

The Director of the Center, after consultation with the advisory council for the Center, [shall prepare for inclusion in the biennial report made under section 403 a biennial] *may prepare a* report which shall consist of a description of the activities of the Center and program policies of the Director of the Center in the fiscal years respecting which the report is prepared. The Director of the Center may prepare such additional reports as the Director determines appropriate. The Director of the Center shall provide the ad-

visory council for the Center an opportunity for the submission of the written comments referred to in section 480(g).

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SEC. 486(d)(5)(B) The report required in subparagraph (A) shall be submitted to the Director of NIH [for inclusion in the report required in section 403].

* * * * * * *

SEC. 486B. [(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 4030.]

(b) Submission.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH.

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SEC. 492B. (f) REPORTS BY ADVISORY COUNCILS.

The advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved [for inclusion in the biennial report under section 403.] *and the Director of NIH.*

* * * * * * *

SEC. 417B. (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appropriated [$2,728,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *$3,000,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

(b)(1)(A) For the purpose of carrying out subparagraph (A) of section 417(c)(1), there are authorized to be appropriated [$225,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.* Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purposes.

(B) For the purpose of carrying out subparagraphs (B) through (E) of section 417(c)(1), there are authorized to be appropriated [$100,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.* Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purposes.

(2) OTHER CANCERS.—For the purpose of carrying out subsection (d) of section 417, there are authorized to be appropriated [$75,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.* Such authorizations of appropriations are in addition to the author-

izations of appropriations established in subsection (a) with respect to such purposes.

(c) PROSTATE CANCER.—For the purpose of carrying out section 417A, there are authorized to be appropriated [$72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.* Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purposes.

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SEC. 403A. (e) AUTHORIZATION OF APPROPRIATIONS.

In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through [1996] *1999.*

* * * * * * *

SEC. 425. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this subpart, there are authorized to be appropriated [$1,500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *$1,600,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

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TITLE IV, PART C, SUBPART 6

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SEC. 447(b) For the purpose of carrying out subsection (a), there are authorized to be appropriated [$50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.* Such authorization is in addition to any other authorization of appropriations that is available for such purpose.

* * * * * * *

SEC. 2313(e). AUTHORIZATION OF APPROPRIATIONS.—

(1) For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through [1996] *1999.*

(2) For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through [1996] *1999.*

* * * * * * *

SEC. 452A(g) For the purpose of carrying out this section, there are authorized to be appropriated [$30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

* * * * * * *

SEC. 445I. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this subpart, there are authorized to be appropriated [$500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *$550,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

* * * * * * *

SEC. 464H(d)(1). AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this subpart, there are authorized to be appropriated [$300,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.] *$330,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

* * * * * * *

SEC. 464I. [(b) The] *(b)(1) The* Secretary shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purpose of any land or the purpose, construction, preservation, or repair of any building. [For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).]

(2) As used in paragraph (1), the terms "construction" and "cost of construction" include—

(A) the construction of new buildings, the expansion of existing buildings, and the acquisition, remodeling, replacement, renovation, major repair (to the extent permitted by regulations), or alteration of existing buildings, including architects' fees, but not including the cost of the acquisition of land or offsite improvements; and

(B) the initial equipping of new buildings and of the expanded, remodeled, repaired, renovated, or altered part of existing buildings; except that

such term shall not include the construction or cost of construction of so much of any facility as is used or is to be used for sectarian instruction or as a place for religious worship.

* * * * * * *

SEC. 464L(d)(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, other than section 464P, there are authorized to be appropriated [$440,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.] *$480,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

* * * * * * *

SEC. 464P(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated [$85,000,000 for fiscal year 1993, and $95,000,000 for fiscal year 1994.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

* * * * * * *

SEC. 464N [(b)The] *(b)(1) The* Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. [For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 701(1).]

(2) As used in paragraph (1), the terms "construction" and "cost of construction" include—

(A) the construction of new buildings, the expansion of existing buildings, and the acquisition, remodeling, replacement, renovation, major repair (to the extent permitted by regulations), or alternation of existing buildings, including architects' fees, but not including the cost of the acquisition of land or offsite improvements; and

(B) the initial equipping of new buildings and of the expanded, remodeled, repaired, renovated, or altered part of existing buildings; except that

such term does not include the construction or cost of construction of so much of any facility as is used or is to be used for sectarian instruction or as a place for religious worship.

* * * * * * *

SEC. 464R(f)(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated [$675,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.] *$750,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

* * * * * * *

SEC. 481A(h) For the purpose of carrying out this section, there are authorized to be appropriated [$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

* * * * * * *

SEC. 481B(a) With respect to activities carried out by the National Center for Research Resources to support regional centers for research on primates, the Director of NIH [shall] *may* for each of the fiscal years [1994 through 1996] *1997 through 1999,* reserve from the amounts appropriated under section 481A(h) [$5,000,000] *such sums as may be necessary for each such fiscal year* for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

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TITLE IV, PART B

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SEC. 409C. GENERAL CLINICAL RESEARCH CENTERS.

(a) GRANTS.—The Director of the National Center for Research Resources shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

(b) ACTIVITIES.—In carrying out subsection (a), the Director of NIH shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to make grants under subsection (a), such sums as may be necessary for each of the fiscal years 1996 and 1999.

SEC. 409D. ENHANCEMENT AWARDS.

(a) CLINICAL RESEARCH CAREER ENHANCEMENT AWARD.—

(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as "clinical research career enhancement awards") to support individual careers in clinical research.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) LIMITATIONS.—The amount of a grant under this subsection shall not exceed $130,000 per year per grant. Grants shall be for terms of 5 years. The Director shall award not more than 20 grants in the first fiscal year in which grants are awarded under this subsection. The total number of grants awarded under this subsection for the first and second fiscal years in which such grants are awarded shall not exceed 40 grants.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to make grants under paragraph (1), such sums as may be necessary for each of the fiscal years 1997 through 1999.

(b) INNOVATIVE MEDICAL SCIENCE AWARD.—

(1) IN GENERAL.—The Director of the National Center for Research Resources shall make grants (to be referred to as "innovative medical science awards") to support individual clinical research projects.

(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

(3) LIMITATIONS.—The amount of a grant under this subsection shall not exceed $100,000 per year per grant.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to make grants under paragraph (1), such sums as may be necessary for each of the fiscal years 1997 through 1999.

(c) PEER REVIEW.—The Director of NIH, in cooperation with the Director of the National Center for Research Resources, shall establish peer review mechanisms to evaluate application for clinical research fellowships, clinical research career enhancement awards, and innovative medical science award programs. Such review mech-

anisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research trainees.

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SEC. 481A(b)(3)(A) Subject to subparagraph (B), the Board shall be composed of [9] *12* appointed members, and such ex officio members as the Director of the Center determines to be appropriate.

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(e)(1)(A) [50] *40* percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, [40] *30* percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

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(4) The limitations imposed by paragraph (1) may be waived at the discretion of the Director [for applicants meeting the conditions described in paragraphs (1) and (2) of subsection (c)].

* * * * * * *

(h) For the purpose of carrying out this section, there are authorized to be appropriated [$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

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SEC. 468(a) For the purpose of carrying out this part, there are authorized to be appropriated [$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *$160,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.*

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SEC. 474(b)(2) Grant to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may be regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed [$1,000,000] *$1,250,000.*

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SEC. 487A(a) The Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct, as employees of the National Institutes of health, research with respect to acquired immune deficiency syndrome in consideration of the Federal Government agreeing to repay, for each year of such service, not more than [$20,000] *$35,000* of the principal and interest of the educational loans of such health professionals.

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(c) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through [1996] *1999*.

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SEC. 487B(a) The Secretary, in consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program of entering into contracts with qualified health professionals (including graduate students) under which such health professionals agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than [$20,000] *$35,000* of the principal and interest of the educational loans of such health professionals.

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SEC. 487C(a)(1) Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than [$20,000] *$35,000* of the principal and interest of the educational loans of such health professionals.

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SEC. 487E(a)(1) Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research as employees of the National Institutes of Health in consideration of the Federal Government agreeing to pay, for each year of such service, not more than [$20,000] *35,000* of the principal and interest of the educational loans of the health professionals.

* * * * * * *

(3) Except to the extent inconsistent with this section, the provisions of sections [338C] *338B, 338C* and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

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TITLE IV, PART G

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SEC. 487F. GENERAL LOAN REPAYMENT PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary, acting through the Director of NIH, shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research with respect to the areas identified under paragraph (2) in consideration of

the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such health professionals.

(2) RESEARCH AREAS.—In carrying out the program under paragraph (1), the Director of NIH shall annually identify areas of research for which loan repayments made be awarded under paragraph (1).

(3) TERM OF AGREEMENT.—A loan repayment agreement under paragraph (1) shall be for a minimum of two years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

(c) Authorization of Appropriations.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1997 through 1999.

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SEC. 487(a)(1)(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggregate [50 such] 100 such contracts during the fiscal years 1994 through [1996] *1999*.

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SEC. 487E. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS [FROM DISADVANTAGED BACKGROUNDS].

(a)(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals [who are from disadvantaged backgrounds] under which such health professionals agree to conduct clinical research as employees of the National Institutes of Health in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of the health professionals.

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(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS. [Amounts] *(1) IN GENERAL.—Amounts* appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

(2) DISADVANTAGED BACKGROUNDS SET-ASIDE.—In carrying out this section, the Secretary shall ensure that not less than 50 percent of the amounts appropriated for a fiscal year are used for contracts involving those appropriately qualified health professionals who are from disadvantaged backgrounds.

(c) CLINICAL RESEARCH TRAINING POSITION.—A position shall be considered a clinical research training position under subsection (a)(1) if such position involves an individual serving in a general

clinical research center or other organizations and institutions determined to be appropriate by the Director of NIH, or a physician receiving a clinical research career enhancement award or NIH intramural research fellowship.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each fiscal year.

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SEC. 2353(d)(1) For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 **[**through 1996**]** *through 1999.*

SEC. 2356(g)(1) For the purpose of providing amounts for the Fund, there is authorized to be appropratied **[**$100,000,000 for each of the fiscal years 1994 through 1996.**]** *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

* * * * * * *

SEC. 402(b)(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title; **[**and**]**

(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b)**[**.**]***;*

(13) may conduct and support research training—

(A) for which fellowship support is not provided under section 487; and

(B) which does not consist of residency training of physicians or other health professionals; and

(14) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5, United States Code, relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38, United States Code.

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TITLE IV, PART A

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SEC. 404F. OFFICE FOR RARE DISEASE RESEARCH.

(a) ESTABLISHMENT.—There is established within the Office of the Director of the National Institutes of Health an office to be known as the Office for Rare Disease Research (in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of the National Institutes of Health.

(b) PURPOSE.—The purpose of the Office is to promote and coordinate the conduct of research on rare diseases through a strategic research plan and to establish and manage a rare disease research clinical database.

(c) ADVISORY COUNCIL.—The Secretary shall establish an advisory council for the purpose of providing advice to the director of the Office concerning carrying out the strategic research plan and other duties under this section. Section 222 shall apply to such council to

the same extent and in the same manner as such section applies to committees or councils established under such section.

(d) DUTIES.—In carrying out subsection (b), the director of the Office shall—

(1) develop a comprehensive plan for the conduct and support of research on rare diseases;

(2) coordinate and disseminate information among the institutes and the public on rare diseases;

(3) support research training and encourage the participation of a diversity of individuals in the conduct of rare disease research;

(4) identify projects or research on rare diseases that should be conducted or supported by the National Institutes of Health;

(5) develop and maintain a central database on current government sponsored clinical research projects for rare diseases;

(6) determine the need for registries of research subjects and epidemiological studies of rare disease populations; and

(7) prepare biennial reports on the activities carried out or to be carried out by the Office and submit such reports to the Secretary and the Congress.

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SEC. 487(d) For the purpose of carrying out this section, there are authorized to be appropriated [$400,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.* Of the amounts appropriated under this subsection—

* * * * * * *

SEC. 499(m)(1) For the purpose of carrying out this part, there is authorized to be appropriated [an aggregate $200,000 for the fiscal years 1994 and 1995.] *such sums as may be necessary for each of the fiscal years 1997 through 1999.*

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TITLE IV, PART A

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SEC. 404G. ESTABLISHMENT OF NATIONAL FUND FOR HEALTH RESEARCH.

(a) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the "National Fund for Health Research" (hereafter in this section referred to as the "Fund"), consisting of such amounts as are transferred to the Fund and any interest earned on investment of amounts in the Fund.

(b) OBLIGATIONS FROM FUND.—

(1) IN GENERAL.—Subject to the provisions of paragraph (2), with respect to the amounts made available in the Fund in a fiscal year, the Secretary shall distribute all of such amounts during any fiscal year to research institutes and centers of the National Institutes of Health in the same proportion to the total amount received under this section, as the amount of annual appropriations under appropriations Acts for each member institute and centers for the fiscal year bears to the total amount

of appropriations under appropriations Acts for all research institutes and centers of the National Institutes of Health for the fiscal year.

(2) TRIGGER AND RELEASE OF MONIES.—No expenditure shall be made under paragraph (1) during any fiscal year in which the annual amount appropriated for the National Institutes of Health is less than the amount so appropriated for the prior fiscal year.

SEC. 404H. DEFINITION OF CLINICAL RESEARCH.

As used in this title, the term "clinical research" means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations, or on material of human origin (such as issue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology, or disease, epidemiologic or behavioral studies, outcomes research, or health services research.

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SEC. 288 * * *

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(h) Notwithstanding any other provision of law, the Secretary shall be treated as a non-profit entity for the purposes of making contributions to the retirement systems of appointees under this section in a manner that will permit such appointees to continue to be fully covered under the retirement systems that such appointees were members of immediately prior to their appointment under this section.

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TITLE IV, PART A

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SEC. 404I. PEDIATRIC RESEARCH INITIATIVE.

(a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (hereafter in this section referred to as the "Initiative"). The Initiative shall be headed by the Director of NIH.

(b) PURPOSE.—The purpose of the Initiative is to provide funds to enable the Director of NIH to encourage—

(1) increased support for pediatric biomedical research within the National Institutes of Health to ensure that the expanding opportunities for advancement in scientific investigations and care for children are realized;

(2) enhanced collaborative efforts among the Institutes to support multidisciplinary research in the areas that the Director deems most promising;

(3) increased support for pediatric outcomes and medical effectiveness research to demonstrate how to improve the quality of children's health care while reducing cost;

(4) the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population; and

(5) recognition of the special attention pediatric research deserves.

(c) DUTIES.—In carrying out subsection (b), the Director of NIH shall—

(1) consult with the Institutes and other advisors as the Director determines appropriate when considering the role of the Institute for Child Health and Human Development;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the—

(A) assistance is directly related to the illnesses and diseases of children; and

(B) assistance is extramural in nature; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and be accountable with respect to such funds to Congress and to the public.

(d) AUTHORIZATION.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal years 1997 through 1999.

(e) TRANSFER OF FUNDS.—The Director of NIH may transfer amounts appropriated to any of the Institutes for a fiscal year to the Initiative to carry out this section.

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TITLE IV, PART B

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PARKINSON'S DISEASE

SEC. 409E. (a) IN GENERAL.—The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease.

(b) INTER-INSTITUTE COORDINATION.—

(1) IN GENERAL.—The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson's research.

(2) CONFERENCE.—Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

(c) MORRIS K. UDALL RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of NIH shall award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's. The Director shall award not more than 10 Core Center

Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

(2) REQUIREMENTS.—

(A) IN GENERAL.—With respect to Parkinson's, each center assisted under this subsection shall—

(i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and

(ii) conduct basic and clinical research.

(B) DISCRETIONARY REQUIREMENTS.—With respect to Parkinson's, each center assisted under this subsection may—

(i) conduct training programs for scientists and health professionals;

(ii) conduct programs to provide information and continuing education to health professionals;

(iii) conduct programs for the dissemination of information to the public;

(iv) develop and maintain, where appropriate, a brain bank to collect specimens related to the research and treatment of Parkinson's;

(v) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's, and where possible, comparing relevant data involving general populations;

(vi) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and

(vii) separately or in collaboration with other centers, establish a national education program that foster's a national focus on Parkinson's and the care of those with Parkinson's.

(3) STIPENDS REGARDING TRAINING PROGRAMS.—A center may use funds provided under paragraph (1) to provide stipends for scientists and health professionals enrolled in training programs under paragraph (2)(B).

(4) DURATION OF SUPPORT.—Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) MORRIS K. UDALL AWARD FOR INNOVATION IN PARKINSON'S DISEASE RESEARCH.—The Director of NIH shall establish a grant program to support innovative proposals leading to significant breakthroughs in Parkinson's research. Grants under this subsection shall be available to support outstanding neuroscientists and clinicians who bring innovative ideas to bear on the understanding of the pathogenesis, diagnosis and treatment of Parkinson's disease.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated

$80,000,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 and 1999.

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SEC. 403(5) the biennial reports of the Directors of each of the national research institutes, the Director of the [Division of Research Resources] *National Center for Research Resources,* and the Director of the [National Center for Nursing Research] *National Institute of Nursing Research.*

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SEC. 408(a)(2) Paragraph (1) does not apply to the National Library of Medicine, the [National Center for Nursing Research] *National Institute of Nursing Research,* the John E. Forgarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

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SEC. 406(b)(2)(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the [Chief Medical Director of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of Veterans Affairs,* and the Assistant Secretary of Defense of Health Affairs (or the designees of such officers), and

* * * * * * *

(h)(2)(A)(v) the ex officio members of the board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology policy, the Director of NIH, the [Chief Medical Director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of Veterans Affairs,* the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of energy (or the designees of such officers); and

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SEC. 424(c)(3)(B)(x) The [Chief Medical Director of the Veterans' Administration] *Under Secretary for Health of the Department of Veterans Affairs.*

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SEC. 429(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the division director of the Institute for the diseases for which the Committee is established [Chief Medical Director of the Veterans' Administration] *Under Secretary for Health of the Department of Veterans Affairs,* and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and

agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

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SEC. 430(b)(2)(A)(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the [Chief Medical director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of Veterans Affairs,* the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

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SEC. 439(b) Each committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the [Chief Medical Director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of Veterans Affairs,* the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the Chairman, but not less often than four times a year.

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SEC. 452(f)(3)(B)(xi) The [Chief Medical Director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of Veterans Affairs.*

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SEC. 466(a)(1)(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the [Chief Medical Director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of Veterans Affairs* the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

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SEC. 480(b)(2)(A) the Secretary, the Director of NIH, the Director of the Center, the [Chief Medical Director of the Department of Veterans Affairs] *Under Secretary for Health of the Department of*

Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

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SEC. 406(h)[(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the date of enactment of the Health Research Extension Act of 1985 (Nov. 20, 1985). After such date—

[(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

[(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

[(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.]

[(2)(A) The] *(1) The* National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

[(i)] *(A)* appointments to such Board shall be made by the President;

[(ii)] *(B)* the term of office of an appointed member shall be 6 years;

[(iii)] *(C)* of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

[(iv)] *(D)* the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

[(v)] *(E)* the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy (or the designees of such officers); and

[(vi)] *(F)* the Board shall meet at least four times each fiscal year.

[(B)] *(2)* This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

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[SEC. 430. ADVISORY BOARDS.

[(a) ESTABLISHMENT.—The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an "Advisory Board").

[(b) MEMBERSHIP; EX OFFICIO MEMBERS.—Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

[(1) THE SECRETARY SHALL APPOINT—

[(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

[(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

[(2)(A) The following shall be ex officio members of each Advisory Board:

[(i) The Assistant Secretary for Health, and Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs (Under Secretary for Health of the Department of Veterans Affairs), the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

[(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

[(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

[(c) COMPENSATION.—Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the

General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

[(d) TERM OF OFFICE; VACANCY.—The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

[(e) CHAIRMAN.—The members of each Advisory Board shall select a chairman from among the appointed members.

[(f) EXECUTIVE DIRECTOR; PROFESSIONAL AND CLERICAL STAFF; ADMINISTRATIVE SUPPORT SERVICES AND FACILITIES.—The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support and services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

[(g) MEETINGS.—Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

[(h) FUNCTIONS OF NATIONAL DIABETES ADVISORY BOARD AND NATIONAL DIGESTIVE DISEASES ADVISORY BOARD.—The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

[(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

[(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

[(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

[(i) Subcommittees; establishment and membership. In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such

meetings as are necessary to enable them to carry out their activities.

[(j) ANNUAL REPORT.—Each Advisory Board shall prepare an annual report for the Secretary which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

[(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

[(4) contains the Advisory Board's recommendations (if any) for changes in the plan referred to in section 433.

[(k) TERMINATION OF PREDECESSOR BOARDS; TIME WITHIN WHICH TO APPOINT MEMBERS.—The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Board's established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence in the date of enactment of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes first established under subsection (a).]

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[SEC. 442. ADVISORY BOARD.

[(a) ESTABLISHMENT.—The Secretary shall establish in the Institute the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board (hereafter in this section referred to as the "Advisory Board").

[(b) MEMBERSHIP, EX OFFICIO MEMBERS.—The Advisory Board shall be composed of twenty appointed members and nonvoting, ex officio members, as follows:

[(1) the Secretary shall appoint—

[(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

[(B) eight members from the general public who are knowledgeable with respect to such diseases, including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nurs-

ing, data systems, public information, or community program development.

[(2) The following shall be ex officio members of the Advisory Board:

[(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs (Under Secretary for Health of the Department of Veterans Affairs), and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

[(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

[(c) COMPENSATION.—Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

[(d) TERM OF OFFICE; VACANCY.—The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the vacancy occurred.

[(e) CHAIRMAN.—The members of the Advisory Board shall select a chairman from among the appointed members.

[(f) EXECUTIVE DIRECTOR, PROFESSIONAL AND CLERICAL STAFF, ADMINISTRATIVE SUPPORT, SERVICES AND FACILITIES.—The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

[(g) MEETINGS.—The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

[(h) DUTIES AND FUNCTIONS.—The Advisory Board shall—

[(1) review and evaluate the implementation of the plan prepared under section 436(a) periodically update the plan to ensure its continuing relevance;

[(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

[(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

[(i) SUBCOMMITTEES ESTABLISHMENT AND MEMBERSHIP.—In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

[(j) ANNUAL REPORT.—The Advisory Board shall prepare an annual report for the Secretary which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

[(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made;

[(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a); and

[(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal disease.

[(k) TERMINATION OF PREDECESSOR BOARD; TIME WITHIN WHICH TO APPOINT MEMBERS.—The National Arthritis Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such date. The member of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).]

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TITLE IV, PART C, SUBPART 6

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SEC. [447] *447A* RESEARCH CENTERS REGARDING CHRONIC FATIGUE SYNDROME.

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[SEC. 464D. NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY BOARD.

[(a) ESTABLISHMENT.—the Secretary shall establish in the Institute the National Deafness and Other communication Disorders Advisory Board (hereafter in this section referred to as the "Advisory Board").

[(b) COMPOSITION; QUALIFICATIONS; APPOINTED AND EX OFFICIO MEMBERS.—The Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

[(1) The Secretary shall appoint—

[(A) twelve members from individuals who are scientists, physicians, and other health and rehabilitation professionals, who are not officers or employees of the United States, and who represent the specialities and disciplines relevant to deafness and other communication disorders, including not less than two persons with a communication disorder; and

[(B) six members from the general public who are knowledgeable with respect to such disorders, including not less than one person with a communication disorder and not less than one person who is a parent of an individual with such a disorder.

Of the appointed members, not less than five shall by virtue of training or experience by knowledgeable in diagnoses and rehabilitation of communication disorders, education of the hearing, speech, or language impaired, public health, public information, community program development, occupational hazards to communications senses, or the aging process.

[(2) The following shall be ex officio members of each Advisory Board:

[(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute on Deafness and Other Communication Disorders, the Director of the Centers for Disease Control and Prevention, the Chief Medical Director of the Department of Veterans Affairs (Under Secretary for Health of the Department of Veterans Affairs), and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers).

[(B) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

[(c) COMPENSATION.—Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

[(d) TERM OF OFFICE; VACANCIES.—The term of office of an appointed member of the Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member

may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

[(e) CHAIRMAN.—The members of the Advisory Board shall select a chairman from among appointed members.

[(f) PERSONNEL; EXECUTIVE DIRECTOR; PROFESSIONAL AND CLERICAL STAFF MEMBERS; CONSULTANTS; AND ADMINISTRATIVE SUPPORT SERVICES AND FACILITIES.—The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

[(g) MEETINGS.—The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

[(h) FUNCTIONS.—The Advisory Board shall—

[(1) review and evaluate the implementation of the plan prepared under section 464A(a) and periodically update the plan to ensure its continuing relevance;

[(2) for the purpose of assuring the most effective use and organization of resources respecting deafness and other communication disorders, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

[(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan and with key non-Federal entities involved in activities affecting the control of such disorders.

[(i) Subcommittee activities; workshops and conferences; collection of data. In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

[(j) ANNUAL REPORT.—The Advisory Board shall prepare an annual report for the Secretary which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the deafness and other communication disorders;

[(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such disorders in such fiscal year; and

[(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 464A(a).

[(k) COMMENCEMENT OF EXISTENCE.—The National Deafness and Other Communication Disorders Advisory Board shall be established not later than April 1, 1989.]

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SEC. 489 [(b) ARRANGEMENT WITH NATIONAL ACADEMY OF SCIENCES OR OTHER NONPROFIT PRIVATE GROUPS OR ASSOCIATIONS.

[(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

[(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

[(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.]

[(c)] *(b)* REPORT TO CONGRESSIONAL COMMITTEES.—A report on the results of the study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least once every four years.

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COMPREHENSIVE ALCOHOL ABUSE AND ALCOHOLISM PREVENTION, TREATMENT, AND REHABILITATION ACT AMENDMENTS OF 1979

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[National Commission on Alcoholism and Other Alcohol Related Problems, establishment; Executive Secretary; interim and final reports of study; termination; authorization of appropriations.

[Section 18. Jan. 2, 1980, P.L. 96–180, Sec. 18, 93 Stat. 1306; Apr. 26, 1983, P.L. 98–24, Sec. 5(a)(2), 97 Stat. 183, provided that:

["(a)(1) There is established a Commission to be known as the National Commission on Alcoholism and Other Alcohol-Related Problems (hereinafter in this section referred to as the 'Commission'). The Commission shall be composed of —

["(A) four Members of the Senate appointed by the President of the Senate upon the recommendation of the majority and minority leaders;

["(B) four Members of the House of Representatives appointed by the Speaker of the House of Representatives upon the recommendation of the majority and minority leaders;

["(C) nine public members appointed by the President; and

[“(D) not more than four nonvoting members appointed by the President from individuals employed in the administration of programs of the Federal Government which affect the prevention and treatment of alcoholism and the rehabilitation of alcoholics and alcohol abusers. At no time shall more than two members appointed under subparagraph (A), more than two of the members appointed under subparagraph (B), or more than five of the members appointed under subparagraph (C) be members of the same political party.

[“(2)(A) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Nine members of the Commission shall constitute a quorum, but a lesser number may conduct hearings. Members appointed under paragraph (1)(D) shall not be considered in determining a quorum of the Commission.

[“(B) Members of the Commission shall serve without compensation, but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission.

[“(C) The Commission shall meet at the call of the Chairman or at the call of the majority of the members thereof.

[“(3)(A) The Commission may appoint, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, an executive secretary to assist the Commission in carrying out its functions.

[“(B) The Secretary shall provide the Commission with such additional professional and clerical staff, such information, and the services of such consultants as the Secretary determines necessary for the Commission to carry out effectively its functions.

[“(C) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Commissions, the head of such department or agency shall furnish such information to the Commission consistent with applicable laws and regulations with respect to the privacy of medical records.

[“(b) The Commission shall conduct a study of alcoholism and alcohol-related problems and shall include in the study—

[“(1) an assessment of unmet treatment and rehabilitation needs of alcoholics and their families;

[“(2) an assessment of personnel needs in the fields of research, treatment, rehabilitation, and prevention;

[“(3) an assessment of the integration and financing of alcoholism treatment and rehabilitation into health and social health care services within communities;

[“(4) a study of the relationship of alcohol use to aggressive behavior and crime;

[“(5) a study of the relationship of alcohol use to family violence;

[“(6) a study of the relationship of alcoholism to illnesses, particularly those illnesses with a high stress component, among family members of alcoholics;

[“(7) an evaluation of the effectiveness of prevention programs, including the relevance of alcohol control laws and regulations to alcoholism and alcohol-related problems;

[“(8) a survey of the unmet research needs in the area of alcoholism and alcohol-related problems;

[“(9) a survey of the prevalence of occupational alcoholism and alcohol abuse programs offered by Federal contractors; and

[“(10) an evaluation of the needs of special and underserved population groups, including American Indians, Alaskan Natives, native Hawaiians, Native American Pacific Islanders, youth, the elderly, women, and the handicapped and assess the adequacy of existing services to fulfill such needs.

[“(c) The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

[“(d) The Secretary of Health, Education, and Welfare shall be responsible for the coordination of the activities of the Commission.

[“(e) There are authorized to be appropriated for the purposes of this section $1,000,000 to remain available until the expiration of the Commission.”.]

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COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT OF 1980

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SEC. 311(a) [(5) ADVISORY COUNCIL.—To assist in the implementation of this subsection and to aid in the coordination of research and demonstration and training activities funded from the Fund under this section, the Secretary shall appoint an advisory council (hereinafter in this subsection referred to as the “Advisory Council”) which shall consist of representatives of the following:

[(A) The relevant Federal agencies.

[(B) The chemical industry.

[(C) The toxic waste management industry.

[(D) Institutions of higher education.

[(E) State and local health and environmental agencies.

[(F) The general public.

(6) PLANNING.—Within nine months after the date of the enactment of this subsection (enacted Oct. 17, 1986), the Secretary, acting through the Director of the National Institute for Environmental Health Sciences, shall issue a plan for the implementation of paragraph (1). The plan shall include priorities for actions under paragraph (1) and include research and training relevant to scientific and technological issues resulting from the site specific hazardous substance response experience. The Secretary shall, to the maximum extent practicable, take appropriate steps to coordinate program activities under this plan with the activities of other Fed-

eral agencies in order to avoid duplication of effort. The plan shall be consistent with the need for the development of new technologies for meeting the goals of response actions in accordance with the provisions of this Act. The Advisory Council shall be provided an opportunity to review and comment on the plan and priorities and assist appropriate coordination among [the relevant Federal agencies referred to in subparagraph (A) of paragraph (5)] *relevant Federal agencies.*

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